



SELECT HEALTH

PHARMACY

PRIOR AUTHORIZATION CRITERIA

MAY 2010

SELECT HEALTH PRIOR AUTHORIZATION CRITERIA

ACCUTANE (isotretinoin) Capsule: 10mg, 20mg, 30mg, 40mg

STATUS Preferred

PA CRITERIA FOR APPROVAL

- Diagnosis of severe recalcitrant nodular acne.

If the above condition is met, the request will be approved with a 3 month duration; if the above conditions are not met, the request will be referred to a Pharmacist for medical necessity review.

FDA INDICATIONS

Isotretinoin is indicated for the treatment of severe recalcitrant nodular acne.

DOSAGE AND ADMINISTRATION

The recommended dosage range for isotretinoin is 0.5-1.0mg/kg/day given in two divided doses with food for 15-20 weeks. The safety of once daily dosing with isotretinoin has not been established. Once daily dosing is not recommended. In studies comparing 0.1, 0.5, and 1.0mg/kg/day, it was found that all dosages provided initial clearing of disease, but there was a greater need for retreatment with the lower dosages. During treatment, the dose may be adjusted according to response of the disease and/or the appearance of clinical side effects – some of which may be dose related. Adult patients whose disease is very severe with scarring or is primarily manifested on the trunk may require dose adjustments up to 2.0mg/kg/day, as tolerated. Failure to take isotretinoin with food will significantly decrease absorption. Before upward dose adjustments are made, the patients should be questioned about their compliance with food instructions. If the total nodule count has been reduced by more than 70% prior to completing 15-20 weeks of treatment, the drug may be discontinued. After a period of 2 months or more off therapy, and if warranted by persistent or recurring severe nodular acne, a second course of therapy may be initiated. The optimal interval before retreatment has not been defined for patients who have not completed skeletal growth. Long-term use of isotretinoin, even in low doses, has not been studied, and is not recommended.

REFERENCES

1. Accutane. Prescribing Information. Roche Pharmaceuticals. January 2010.
2. Facts and Comparisons, St. Louis, 2010 eFacts CliniSphere Version ISBN 1-57439-036-8.
3. Johnson BA, Nunley JR. Use of systemic agents in the treatment of acne vulgaris. Am Fam Physician. 2000 Oct 15;62(8):1823-30, 1835-6.

Revision/Review Date: 5/2010

Associated Policy: Prior Authorization of Medications 236.200

NOTE: Pharmacist reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.

SELECT HEALTH PRIOR AUTHORIZATION CRITERIA

TOPICAL ANDROGENS

STATUS Preferred, Pays at Point-of-Sale (First Line)

ANDROGEL (testosterone) Gel: 25mg/2.5gm, 50mg/5gm; Pump: 1%

STATUS Non-Preferred, Requires Prior Authorization (Second Line)

ANDRODERM (testosterone) Patch: 2.5mg/24hr, 5mg/24hr

TESTIM (testosterone) Gel: 1%

PA CRITERIA FOR APPROVAL

INITIAL PA:

- Male patient.
- Diagnosis of primary hypogonadism (congenital or acquired) or hypogonadotropic hypogonadism (congenital or acquired).
- Documented testosterone level(s) below 300ng/dL.
- Documented trial and failure with therapeutic doses or intolerance to Androgel.

If the above conditions are met, the request will be approved with a 3 month duration; if the above conditions are not met, the request will be referred to a Pharmacist for medical necessity review.

RENEWAL PA:

- Repeat documented testosterone level(s) below 300ng/dL.

If the above conditions are met, the request will be approved with a 3 month duration; if the above conditions are not met, the request will be referred to a Pharmacist for medical necessity review.

FDA INDICATIONS

AndroGel, Androderm & Testim are indicated for testosterone replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone:

- **Primary Hypogonadism (Congenital or Acquired):** Testicular failure due to cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, orchiectomy, Klinefelter's syndrome, chemotherapy, or toxic damage from alcohol or heavy metals. These men usually have low serum testosterone levels and gonadotropins (FSH, LH) above the normal range.
- **Hypogonadotropic Hypogonadism (Congenital or Acquired):** Idiopathic gonadotropin or luteinizing hormone-releasing hormone (LHRH) deficiency or pituitary-hypothalamic injury from tumors, trauma, or radiation. These men have low testosterone serum levels but have gonadotropins in the normal or low range.

NOTE: AndroGel & Testim has not been clinically evaluated in males less than 18 years of age.

NOTE: Androderm has not been clinically evaluated in males less than 15 years of age.

DOSAGE AND ADMINISTRATION

AndroGel:

The recommended starting dose of AndroGel is 5g delivering 5mg of testosterone systemically, applied once daily (preferably in the morning) to clean, dry, intact skin of the shoulders and upper arms and/or abdomen. Serum testosterone levels should be monitored regularly to ensure proper dosing. If the serum testosterone concentration is below the normal range, or if the desired clinical response is not achieved, the daily AndroGel dose may be increased from 5g to 7.5g and from 7.5g to 10g as instructed by the physician. AndroGel is available in either unit-dose packets or multiple-dose pumps. The metered-dose pump delivers 1.25g of product when the pump mechanism is fully depressed once. AndroGel must not be applied to the genitals. If using the multi-dose AndroGel Pump, patients should be instructed to prime the pump before using it for the first time by fully depressing the pump mechanism (actuation) 3 times and discard this portion of the product to assure precise dose delivery. After the priming procedure, patients should completely depress the pump one time (actuation) for every 1.25g of product required to achieve the daily prescribed dosage. The product may be delivered directly into the palm of the hand and then applied to the desired application sites, either one pump actuation at a time or upon completion of all pump actuations required for the daily dose. Alternatively, the product can be applied directly to the application sites. Application directly to the sites may prevent loss of product that may occur during transfer from the palm of the hand onto the application sites. Please refer to the chart below for specific dosing guidelines when the AndroGel Pump is used.

Prescribed Daily Dose	Number of Pump Actuations
5g	4 (once daily)
7.5g	6 (once daily)
10g	8 (once daily)

If using the packets, the entire contents should be squeezed into the palm of the hand and immediately applied to the application sites. Alternately, patients may squeeze a portion of the gel from the packet into the palm of the hand and apply to application sites. Repeat until entire contents have been applied. Application sites should be allowed to dry for a few minutes prior to dressing. Hands should be washed with soap and water after AndroGel has been applied.

Androderm:

The usual starting dose is one Androderm 5mg system or two Androderm 2.5mg systems applied nightly for 24 hours, providing a total dose of 5mg/day. The adhesive side of the Androderm system should be applied to a clean, dry area of the skin on the back, abdomen, upper arms, or thighs. Avoid application over bony prominences or on a part of the body that may be subject to prolonged pressure during sleep or sitting (e.g., the deltoid region of the upper arm, the greater trochanter of the femur, and the ischial tuberosity). Do not apply to the scrotum. The sites of application should be rotated, with an interval of 7 days between applications to the same site. The area selected should not be oily, damaged, or irritated. The system should be applied immediately after opening the pouch and removing the protective release liner. The system should be pressed firmly in place, making sure there is good contact with the skin, especially around the edges.

Testim:

The recommended starting dose of Testim is 5g of gel (one tube) containing 50mg of testosterone applied once daily (preferably in the morning) to clean, dry intact skin of the shoulders and/or upper arms. Morning serum testosterone levels should then be measured approximately 14 days after initiation of therapy to ensure proper serum testosterone levels are achieved. If the serum testosterone concentration is below the normal range, or if the desired clinical response is not achieved, the daily Testim dose may be increased from 5g (one tube) to 10g (two tubes) as instructed by the physician. Upon opening the tube the entire contents should be squeezed into the palm of the hand and immediately applied to the shoulders and/or upper arms. Application sites should be allowed to dry for a few minutes prior to dressing. Hands should be washed thoroughly with soap and water after Testim has been applied. In order to prevent transfer to another person, clothing should be worn to cover the application sites. If direct skin-to-skin contact with another person is anticipated, the application sites must be washed thoroughly with soap and water. In order to maintain serum testosterone levels in the normal range, the sites of application should not be washed for at least two hours after application of Testim. Do not apply Testim to the genitals or to the abdomen.

REFERENCES

1. AndroGel. Prescribing Information. Solvay Pharmaceuticals, Inc. September 2009.
2. Androderm. Prescribing Information. Watson Pharma, Inc. November 2005.
3. Testim. Prescribing Information. Auxilium Pharmaceuticals, Inc. September 2009.
4. Facts and Comparisons, St. Louis, 2010 eFacts CliniSphere Version ISBN 1-57439-036-8.
5. Seftel AD, Mack RJ, Secret AR, Smith TM. Restorative increases in serum testosterone levels are significantly correlated to improvements in sexual functioning. J Andrology. 25(6):963-72, Nov-Dec 2004.

Revision/Review Date: 2/2010

Associated Policy: Prior Authorization of Medications 236.200

NOTE: Pharmacist reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.

SELECT HEALTH PRIOR AUTHORIZATION CRITERIA

ANZEMET (dolasetron) Tablet: 50mg, 100mg

STATUS Non-Preferred

PA CRITERIA FOR APPROVAL

- Current treatment with emetogenic chemotherapy.
- Documented trial and failure with therapeutic doses or intolerance to ondansetron.

If the above condition is met, the request will be approved with a quantity limit of 5 tablets/30days with a for the duration of the chemotherapy, not to exceed 3 months; if the above condition is not met, the request will be referred to a Pharmacist for medical necessity review. If the request is for a quantity greater than 5 tablets/30days, the request will be referred to a Pharmacist for medical necessity review.

FDA INDICATIONS

- The prevention of nausea and vomiting associated with moderately emetogenic cancer chemotherapy, including initial and repeat courses.
- The prevention of postoperative nausea and vomiting.

DOSAGE AND ADMINISTRATION

Prevention of Cancer Chemotherapy-Induced Nausea and Vomiting:

- Adults: The recommended oral dosage of Anzemet is 100mg given within one hour before chemotherapy.
- Pediatric Patients: The recommended oral dosage in pediatric patients 2-16 years of age is 1.8mg/kg given within one hour before chemotherapy, up to a maximum of 100mg. Safety and effectiveness in pediatric patients under 2 years of age have not been established.

Prevention of Postoperative Nausea and Vomiting:

- Adults: The recommended oral dosage of Anzemet is 100mg within two hours before surgery.
- Pediatric Patients: The recommended oral dosage in pediatric patients 2-16 years of age is 1.2mg/kg given within two hours before surgery, up to a maximum of 100mg. Safety and effectiveness in pediatric patients under 2 years of age have not been established.

REFERENCES

1. Anzemet. Prescribing Information. Patheon Pharmaceuticals, Inc. June 2006.
2. Facts and Comparisons, St. Louis, 2010 eFacts CliniSphere Version ISBN 1-57439-036-8.
3. Bubalo J, Seelig F, Karbowicz S, Maziarz RT. Randomized open-label trial of dolasetron for the control of nausea and vomiting associated with high-dose chemotherapy with hematopoietic stem cell transplantation. Biol Blood Marrow Transplant. 2001;7(8):439-45.
4. The National Comprehensive Cancer Network (NCCN) and The American Cancer Society (ACS). Nausea and Vomiting. Treatment Guidelines for Patients with Cancer. Version 1. January 2001.
5. Steiner M, Yorgason RZ, Vermeulen LC, Theisen J. Patient outcomes after therapeutic interchange of dolasetron for granisetron. Am J Health-Syst Pharm 2003;60(10):1023-8.
6. Markman M. Progress in preventing chemotherapy-induced nausea and vomiting. Cleve Clin J Med 2002 Aug;69(8):609-17.

Revision/Review Date: 2/2010

Associated Policy: Prior Authorization of Medications 236.200

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SELECT HEALTH PRIOR AUTHORIZATION CRITERIA

ATYPICAL ANTIPSYCHOTICS

STATUS Preferred

ABILIFY (aripiprazole) Tablet: 2mg, 5mg, 10mg, 15mg, 20mg, 30mg; Discmelt (Orally Disintegrating Tablet): 10mg, 15mg; Oral Solution: 1mg/mL

CLOZARIL (clozapine) Tablet: 25mg, 50mg, 100mg, 200mg

FAZACLO (clozapine) Orally Disintegrating Tablet: 12.5mg, 25mg, 100mg

GEODON (ziprasidone) Capsule: 20mg, 40mg, 60mg, 80mg

RISPERDAL (risperidone) Tablet: 0.25mg, 0.5mg, 1mg, 2mg, 3mg, 4mg; M-Tab (Orally Disintegrating Tablet): 0.25mg, 0.5mg, 1mg, 2mg, 3mg, 4mg; Oral Solution: 1mg/mL

SEROQUEL (quetiapine) Tablet: 25mg, 50mg, 100mg, 200mg, 300mg, 400mg

SEROQUEL XR (quetiapine extended release) Tablet: 50mg, 150mg, 200mg, 300mg, 400mg

SYMBYAX (olanzapine/fluoxetine) Capsule: 3mg/25mg, 6mg/25mg, 6mg/50mg, 12mg/25mg, 12mg/50mg

ZYPREXA (olanzapine) Tablet: 2.5mg, 5mg, 7.5mg, 10mg, 15mg, 20mg; Zydys (Orally Disintegrating Tablet): 5mg, 10mg, 15mg, 20mg

STATUS Non-Preferred

FANAPT (iloperidone) Tablet: 1mg, 2mg, 4mg, 6mg, 8mg, 10mg, 12mg; Titration Pack

INVEGA (paliperidone) Tablet: 3mg, 6mg, 9mg

SAPHRIS (asenapine) Sublingual Tablet: 5mg, 10mg

PA CRITERIA FOR APPROVAL

- Preferred atypical antipsychotics prescribing in a dose that exceeds FDA approved limits will require prior authorization.
- Requests will be considered based on individual circumstances.
- Factors to be considered include but are not limited to: indication for use, previous therapy, previous dose, concomitant therapy, and side effects of increased/higher doses.

If the above conditions are met, the request will be approved with a 12 month duration; if the above conditions are not met, the request will be referred to a Pharmacist for medical necessity review.

FDA INDICATIONS

Drug	Schizophrenia	Bipolar Disorder	Major Depressive Disorder	Irritability Associated with Autistic Disorder	Recurrent Suicidal Behavior
Abilify	X	X	X		
Clozaril	X				X
Fanapt	X				
Fazaclo	X				X
Geodon	X	X			
Invega	X				
Risperdal	X	X		X	
Seroquel	X	X			
Saphris	X	X			
Seroquel XR	X	X			
Symbyax		X	X		
Zyprexa	X	X			

TARGET & MAXIMUM DAILY DOSAGE

Drug	Target Daily Dosage Range	Maximum Daily Dose
Abilify	10-30mg	30mg
Clozaril	300-600mg	900mg
Fanapt	12-24mg	24mg
Fazaclo	300-600mg	900mg
Geodon	40-160mg	200mg
Invega	3-12mg	12mg
Risperdal	1-8mg	16mg
Saphris	10-20mg	20mg
Seroquel	300-800mg	800mg
Seroquel XR	400-800mg	800mg
Symbyax	6-12mg/25-50mg	18mg/75mg
Zyprexa	10-20mg	20mg

REFERENCES

1. Facts and Comparisons, St. Louis, eFacts 2010 CliniSphere Version ISBN 1-57439-036-8.
2. Abilify. Prescribing Information. Bristol-Myers Squibb Company. November 2008.
3. Clozaril. Prescribing Information. Novartis Pharmaceuticals. March 2008.
4. Fanapt. Prescribing Information. Novartis Pharmaceuticals. July 2009.
5. Fazaclo. Prescribing Information. Azur Pharma, Inc. August 2008.
6. Geodon. Prescribing Information. Pfizer, Inc. August 2008.
7. Invega. Prescribing Information. Janssen. December 2008.
8. Risperdal. Prescribing Information. Janssen. August 2008.
9. Saphris. Prescribing Information. Schering-Plough. August 2009.
10. Seroquel. Prescribing Information. AstraZeneca. January 2009.
11. Seroquel XR. Prescribing Information. AstraZeneca. January 2009.
12. Symbyax. Prescribing Information. Eli Lilly and Company. March 2009.
13. Zyprexa. Prescribing Information. Eli Lilly and Company. March 2009.

Revision/Review Date: 2/2010

Associated Policy: Prior Authorization of Medications 236.200

NOTE: Pharmacist reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.

SELECT HEALTH PRIOR AUTHORIZATION CRITERIA

BANZEL (rufinamide) Tablet: 200mg, 400mg

STATUS Preferred

PA CRITERIA FOR APPROVAL

- Diagnosis of Lennox-Gastaut syndrome.
- Patient is currently receiving another anticonvulsant medication at a therapeutic dosage.

If the above conditions are met, the request will be approved with a 12 month duration; if the above conditions are not met, the request will be referred to a Pharmacist for medical necessity review.

FDA INDICATIONS

- For adjunctive treatment of seizures associated with Lennox-Gastaut syndrome in children 4 years and older and adults.

DOSAGE AND ADMINISTRATION

- *Children Four Years and Older with Lennox-Gastaut Syndrome:* Treatment should be initiated at a daily dose of approximately 10mg/kg/day administered in two equally divided doses. The dose should be increased by approximately 10mg/kg increments every other day to a target dose of 45mg/kg/day or 3200mg/day, whichever is less, administered in two equally divided doses. It is not known whether doses lower than the target doses are effective.
- *Adults with Lennox-Gastaut Syndrome:* Treatment should be initiated at a daily dose of 400-800mg/day administered in two equally divided doses. The dose should be increased by 400-800 mg/day every 2 days until a maximum daily dose of 3200mg/day, administered in two equally divided doses is reached. It is not known whether doses lower than 3200mg are effective.
- Banzel tablets are scored on both sides and can be cut in half for dosing flexibility. Tablets can be administered whole, as half tablets or crushed.
- Banzel should be given with food.

REFERENCES

1. Facts and Comparisons, St. Louis, 2010 eFacts CliniSphere Version ISBN 1-57439-036-8.
2. Banzel. Prescribing Information. Eisai. November 2008.

Revision/Review Date: 2/2010

Associated Policy: Prior Authorization of Medications 236.200

NOTE: Pharmacist reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.

SELECT HEALTH PRIOR AUTHORIZATION CRITERIA

BYETTA (exenatide) Prefilled Pen: 250mcg/mL

STATUS Non-Preferred

PA CRITERIA FOR APPROVAL

- Diagnosis of Type 2 Diabetes Mellitus.
- Documented treatment and failure or contraindication of a maximum dose of metformin-sulfonylurea combination.
- Documented treatment and failure or contraindication of a maximum dose of thiazolidinediones.
- Patient must have good compliance with current antidiabetic therapy.

If the above conditions are met, the request will be approved with a 12 month duration; if the above conditions are not met, the request will be referred to a Pharmacist for medical necessity review.

FDA INDICATIONS

Byetta is indicated as adjunctive therapy to improve glycemic control in patients with Type 2 Diabetes Mellitus who are taking metformin, a sulfonylurea, a thiazolidinedione, a combination of metformin and a sulfonylurea, or a combination of metformin and a thiazolidinedione, but have not achieved adequate glycemic control.

DOSAGE AND ADMINISTRATION

Byetta therapy should be initiated at 5mcg per dose administered twice daily at any time within the 60-minute period before the morning and evening meals (or before the two main meals of the day, approximately 6 hours or more apart). Byetta should not be administered after a meal. Based on clinical response, the dose of Byetta can be increased to 10mcg twice daily after 1 month of therapy. Each dose should be administered as a SC injection in the thigh, abdomen, or upper arm. Byetta is recommended for use in patients with type 2 diabetes mellitus who are already receiving metformin, a sulfonylurea, a thiazolidinedione, a combination of metformin and a sulfonylurea, or a combination of metformin and a thiazolidinedione, and have suboptimal glycemic control. When Byetta is added to metformin or thiazolidinedione therapy, the current dose of metformin or thiazolidinedione can be continued as it is unlikely that the dose of metformin or thiazolidinedione will require adjustment due to hypoglycemia when used with Byetta. When Byetta is added to sulfonylurea therapy, a reduction in the dose of sulfonylurea may be considered to reduce the risk of hypoglycemia.

REFERENCES

1. Kendall DM, Riddle MC, et al. Effects of Exenatide (Exendin-4) on Glycemic Control Over 30 Weeks in Patients With Type 2 Diabetes Treated With Metformin and a Sulfonylurea. *Diabetes Care*. May 2005. 28(5):1083-1091.
2. DeFronzo RA, Ratner RE, et al. Effects of Exenatide (Exendin-4) on Glycemic Control and Weight Over 30 Weeks in Metformin-Treated Patients With Type 2 Diabetes. *Diabetes Care*. May 2005. 28(5):1092-1100.
3. Byetta. Prescribing Information. Amylin Pharmaceuticals, Inc. June 2008.
4. Kahn SE, Haffner SM, Heise MA, et al. Glycemic durability of rosiglitazone, metformin, or glyburide monotherapy. *N Engl J Med*. 2006;355:2427-43.
5. VanDeKoppel S, Choe HM, Sweet BV. Managed Care Perspective on Three New Agents for Type 2 Diabetes. *Journal of Managed Care Pharmacy*. 2008;14(4):363-80.

Revision/Review Date: 8/2009

Associated Policy: Prior Authorization of Medications 236.200

NOTE: Pharmacist reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.

SELECT HEALTH STEP THERAPY CRITERIA

CELEBREX (celecoxib) Capsule: 50mg, 100mg, 200mg, 400mg

STATUS Preferred

PA CRITERIA FOR APPROVAL

Patient Meets One or More of the Following Criteria:

- Age over 60 years.
- Concurrent anticoagulant or antiplatelet therapy (including low-dose aspirin).
- Concurrent or past history of peptic ulcer disease or gastrointestinal hemorrhage.
- Concurrent corticosteroid therapy.

If the above conditions are met, the request will be approved for a 12 month duration; if the above conditions are not met, the request will be to a Pharmacist for medical necessity review.

Documented Gastrointestinal Disease (GERD, Erosive Esophagitis, Barretts Esophagus, Zollinger Ellison Disease):

- Diagnosis of osteoarthritis, rheumatoid arthritis, juvenile rheumatoid arthritis, or ankylosing spondylitis.
- Documented gastrointestinal disease of the following conditions: gastroesophageal reflux disease, erosive esophagitis, Barretts esophagus, or Zollinger Ellison disease, and currently taking either a proton pump inhibitor or an H2 receptor antagonist.

If the above conditions are met, the request will be approved for a 12 month duration; if the above conditions are not met, the request will be to a Pharmacist for medical necessity review.

NSAID Therapy Failure:

- Diagnosis of osteoarthritis, rheumatoid arthritis, juvenile rheumatoid arthritis, or ankylosing spondylitis.
- Documented trial and failure with therapeutic prescription doses or intolerance to at least two preferred NSAIDs.

If the above conditions are met, the request will be approved for a 12 month duration; if the above conditions are not met, the request will be to a Pharmacist for medical necessity review.

Acute Pain:

- Diagnosis of acute pain.
- Documented trial and failure with therapeutic prescription doses or intolerance to at least three preferred NSAIDs.

If the above conditions are met, the request will be approved with a 5 day duration; if the above conditions are not met, the request will be to a Pharmacist for medical necessity review.

Primary Dysmenorrhea:

- Premenopausal female patient.
- Diagnosis of primary dysmenorrhea.
- Documented trial and failure with therapeutic prescription doses or intolerance to at least three preferred NSAIDs.

If the above conditions are met, the request will be approved with a 5 day duration; if the above conditions are not met, the request will be to a Pharmacist for medical necessity review.

Familial Adenomatous Polyposis (FAP):

- Diagnosis of familial adenomatous polyposis (FAP).

If the above conditions are met, the request will be approved for a 12 month duration; if the above conditions are not met, the request will be to a Pharmacist for medical necessity review.

FDA INDICATIONS

- For relief of the signs and symptoms of osteoarthritis.
- For relief of the signs and symptoms of rheumatoid arthritis in adults.
- For relief of the signs and symptoms of juvenile rheumatoid arthritis in patients 2 years and older.
- For the relief of signs and symptoms of ankylosing spondylitis.
- For the management of acute pain in adults.
- For the treatment of primary dysmenorrhea.
- To reduce the number of adenomatous colorectal polyps in familial adenomatous polyposis (FAP), as an adjunct to usual care (ex. endoscopic surveillance, surgery).

DOSAGE AND ADMINISTRATION

- **Osteoarthritis:** 200mg once daily or 100mg twice daily.
- **Rheumatoid Arthritis:** 100-200mg twice daily.
- **Juvenile Rheumatoid Arthritis:** 50mg twice daily (10kg-25kg) or 100mg twice daily (>25kg).
- **Ankylosing Spondylitis:** 200mg once daily or 100mg twice daily. If no effect is observed after 6 weeks, a trial of 400mg daily may be worthwhile. If no effect is observed after 6 weeks on 400mg daily, a response is not likely and consideration should be given to alternate treatment options.
- **Acute Pain:** 400mg initially, followed by an additional 200mg dose if needed on the first day. On subsequent days, the recommended dose is 200mg twice daily as needed.
- **Primary Dysmenorrhea:** 400mg initially, followed by an additional 200mg dose if needed on the first day. On subsequent days, the recommended dose is 200mg twice daily as needed.
- **Familial Adenomatous Polyposis (FAP):** 400mg twice daily with food. Usual medical care for FAP should be continued while on Celebrex.

REFERENCES

1. Celebrex. Prescribing Information. Pfizer. June 2009.
2. Facts and Comparisons, St. Louis, eFacts 2010 CliniSphere Version ISBN 1-57439-036-8.
3. Deeks JJ, Smith LA, Bradley MD. Efficacy, tolerability, and upper gastrointestinal safety of celecoxib for treatment of osteoarthritis and rheumatoid arthritis: systematic review of randomized controlled trials. *BMJ*. 2002 Sep 21;325(7365):619.
4. American College of Rheumatology Subcommittee on Rheumatoid Arthritis Guidelines. Guidelines for the management of rheumatoid arthritis. 2002 Update. *Arthritis and Rheumatism*. February 2002; 46(2):328-46.
5. Phillips RK, Wallace MH, Lynch PM, Hawk E, Gordon GB, Saunders BP, et al. Gastrointestinal toxicity with celecoxib vs. nonsteroidal anti-inflammatory drugs for osteoarthritis and rheumatoid arthritis. *JAMA*. 2000; 284:1247-55.
6. Understanding ulcers, ns aids, and gi bleeding, a consumer health guide. American College of Gastroenterology. Available from: <http://www.acg.gi.org/patients/pdfs/UnderstandGIBleednew.pdf>. Accessed 8 April 2008.

Revision/Review Date: 5/2010

Associated Policy: Prior Authorization of Medications 236.200

NOTE: Pharmacist reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.

SELECT HEALTH PRIOR AUTHORIZATION CRITERIA

DDAVP (desmopressin) Tablet: 0.1mg, 0.2mg; Nasal Spray/Rhinal Tube: 10mcg/spray (0.1mg/mL); Injection: 4mcg/mL

STATUS Preferred

PA CRITERIA FOR APPROVAL

Tablets:

- Diagnosis of primary monosymptomatic nocturnal enuresis in children 6 years of age and older.
- OR**
- Management of temporary polyuria and polydipsia following head trauma or surgery in the pituitary region.
- OR**
- Diagnosis of central cranial (neurogenic) diabetes insipidus.

NOTE: Tablet formulation processes at point-of-sale for patients 6 years of age and older.

If one the above conditions are met, the request will be approved for a 12 month duration; if the above conditions are not met, the request will be referred to a Pharmacist for medical necessity review.

Nasal Spray & Rhinal Tube:

- Diagnosis of central cranial (neurogenic) diabetes insipidus.
- OR**
- Management of temporary polyuria and polydipsia following head trauma or surgery in the pituitary region.

NOTE: Nasal Spray & Rhinal Tube formulations will not be approved for the indication of primary monosymptomatic nocturnal enuresis.

If one the above conditions are met, the request will be approved for a 12 month duration; if the above conditions are not met, the request will be referred to a Pharmacist for medical necessity review.

Injection:

- Diagnosis of Hemophilia A with Factor VIII coagulant activity levels greater than 5%.
- OR**
- Diagnosis of mild to moderate classic von Willebrand's disease (Type I) with factor VIII levels greater than 5%.
- OR**
- Diagnosis of central cranial (neurogenic) diabetes insipidus.
- OR**
- Management of temporary polyuria and polydipsia following head trauma or surgery in the pituitary region.

NOTE: Injection formulation will not be approved for the indication of primary monosymptomatic nocturnal enuresis.

If one the above conditions are met, the request will be approved for a 12 month duration; if the above conditions are not met, the request will be referred to a Pharmacist for medical necessity review.

FDA INDICATIONS

Tablets:

- Management of primary monosymptomatic nocturnal enuresis. It may be used alone or adjunctive to behavioral conditioning or other nonpharmacological intervention. It has been shown to be effective in some cases that are refractory to conventional therapies.
 - Antidiuretic replacement therapy in the management of central cranial diabetes insipidus.
 - Management of temporary polyuria and polydipsia following head trauma or surgery in the pituitary region.
- NOTE:** Ineffective for the treatment of nephrogenic diabetes insipidus.

Nasal Spray & Rhinal Tube:

- Antidiuretic replacement therapy in the management of central cranial diabetes insipidus.
 - Management of temporary polyuria and polydipsia following head trauma or surgery in the pituitary region.
- NOTE:** Ineffective for the treatment of nephrogenic diabetes insipidus.

Injection:

- Indicated for patients with Hemophilia A with Factor VIII coagulant activity levels greater than 5%.
- Indicated for patients with mild to moderate classic von Willebrand's disease (Type I) with factor VIII levels greater than 5%.
- Antidiuretic replacement therapy in the management of central cranial diabetes insipidus.

- Management of temporary polyuria and polydipsia following head trauma or surgery in the pituitary region.
- NOTE:** Ineffective for the treatment of nephrogenic diabetes insipidus.

DOSAGE AND ADMINISTRATION

Tablets:

Primary Monosymptomatic Nocturnal Enuresis: Dosage must be determined for each individual patient and adjusted according to response. Patients previously on intranasal DDAVP therapy can begin tablet therapy the night following (24 hours after) the last intranasal dose. The recommended initial dose for patients age 6 years and older is 0.2mg at bedtime. The dose may be titrated up to 0.6mg to achieve the desired response.

Central Cranial Diabetes Insipidus: Dosage must be determined for each individual patient and adjusted according to the diurnal pattern of response. Response should be estimated by two parameters: adequate duration of sleep and adequate, not excessive, water turnover. Patients previously on intranasal DDAVP therapy should begin tablet therapy twelve hours after the last intranasal dose. During the initial dose titration period, patients should be observed closely and appropriate safety parameters measured to assure adequate response. Patients should be monitored at regular intervals during the course of DDAVP Tablet therapy to assure adequate antidiuretic response. Modifications in dosage regimen should be implemented as necessary to assure adequate water turnover.

Adults and Children: It is recommended that patients be started on doses of 0.05mg (1/2 of the 0.1mg tablet) two times a day and individually adjusted to their optimum therapeutic dose. Most patients in clinical trials found that the optimal dosage range is 0.1mg to 0.8mg daily, administered in divided doses. Each dose should be separately adjusted for an adequate diurnal rhythm of water turnover. Total daily dosage should be increased or decreased in the range of 0.1mg to 1.2mg divided into two or three daily doses as needed to obtain adequate antidiuresis.

Nasal Spray:

Central Cranial Diabetes Insipidus: Dosage must be determined for each individual patient and adjusted according to the diurnal pattern of response. Response should be estimated by two parameters: adequate duration of sleep and adequate, not excessive, water turnover. Patients with nasal congestion and blockage have often responded well to intranasal DDAVP. The usual dosage range in adults is 10-40mcg daily, either as a single dose or divided into two or three doses. Most adults require 20mcg daily in two divided doses. The morning and evening doses should be separately adjusted for an adequate diurnal rhythm of water turnover. For children aged 3 months to 12 years, the usual dosage range is 5-30mcg daily, either as a single dose or divided into two doses. About 1/4 to 1/3 of patients can be controlled by a single daily dose of DDAVP administered intranasally.

Rhinal Tube:

Central Cranial Diabetes Insipidus: This drug is administered into the nose through a soft, flexible plastic rhinal tube which has four graduation marks on it that measure 0.2, 0.15, 0.1 and 0.05mL. The dosage must be determined for each individual patient and adjusted according to the diurnal pattern of response. Response should be estimated by two parameters: adequate duration of sleep and adequate, not excessive, water turnover. Patients with nasal congestion and blockage have often responded to intranasal DDAVP. The usual dosage range in adults is 0.1-0.4mL daily, either as a single dose or divided into three or more doses. Most adults require 0.2mL daily in two divided doses. The morning and evening doses should be separately adjusted for an adequate diurnal rhythm of water turnover. For children aged 3 months to 12 years, the usual dosage range is 0.05-0.3mL daily, either as a single dose or divided into two doses. About 1/4 to 1/3 of patients can be controlled by a single daily dose of DDAVP administered intranasally. Fluid restriction should be observed.

Injection:

Hemophilia A and von Willebrand's disease (Type I): 4mcg/mL is administered as an intravenous infusion at a dose of 0.3mcg DDAVP/kg body weight diluted in sterile physiological saline and infused slowly over 15-30 minutes. In adults and children weighing more than 10kg, 50mL of diluent is recommended; in children weighing 10kg or less, 10mL of diluent is recommended. Blood pressure and pulse should be monitored during infusion. If used preoperatively, it should be administered 30 minutes prior to the scheduled procedure.

Central Cranial Diabetes Insipidus: This formulation is administered subcutaneously or by direct intravenous injection. Dosage must be determined for each patient and adjusted according to the pattern of response. Response should be estimated by two parameters: adequate duration of sleep and adequate, not excessive, water turnover. The usual dosage range in adults is 0.5mL (2mcg) to 1mL (4mcg) daily, administered intravenously or subcutaneously, usually in two divided doses. The morning and evening doses should be separately adjusted for an adequate diurnal rhythm of water turnover. For patients who have been controlled or intranasal DDAVP and who must be switched to the injection form, either because of poor intranasal absorption or because of the need for surgery, the comparable antidiuretic dose of the injection is about one-tenth the intranasal dose.

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2. DDAVP Nasal Spray. Prescribing Information. Sanofi-Aventis. July 2007.
3. DDAVP Rhinal Tube. Prescribing Information. Sanofi-Aventis. July 2007.
4. DDAVP Injection. Prescribing Information. Sanofi-Aventis. July 2007.
5. Facts and Comparisons, St. Louis, 2010 eFacts CliniSphere Version ISBN 1-57439-036-8.
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13. FDA Safety Alerts. Desmopressin Acetate (marketed as DDAVP Nasal Spray, DDAVP Rhinal Tube, DDAVP, and Stimate Nasal Spray). Available from: <http://www.fda.gov/medwatch/safety/2007/safety07.htm#Desmopressin>. Updated 4 December 2007. Accessed 20 December 2007.

Revision/Review Date: 2/2010

Associated Policy: Prior Authorization of Medications 236.200

NOTE: Pharmacist reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.

SELECT HEALTH PRIOR AUTHORIZATION CRITERIA

DIASTAT (diazepam) Rectal Gel: 2.5mg
DIASTAT ACUDIAL (diazepam) Rectal Gel: 10mg, 20mg

STATUS Preferred
STATUS Preferred

PA CRITERIA FOR APPROVAL

- Diagnosis of refractory epilepsy.
- Patient is currently on a stable regimen of antiepileptic agents who requires intermittent use of diazepam to control bouts of increased seizure activity.
- An automatic approval at the point-of-sale will occur if the quantities prescribed do not exceed 3 kits (6 units) per 30 days.

NOTE: Diastat & Diastat Acudial will process at the point-of-sale without prior authorization required if the quantity does not exceed 3 kits (6 units) per 30 days.

If the above conditions are met, the request will be approved for a 3 month duration with a quantity not to exceed 3 kits (6 units) per 30 days; if the above conditions are not met, the request will be referred to a Pharmacist for medical necessity review. If the request is for greater than 3 kits (6 units), the request will be referred to a Pharmacist for medical necessity review.

FDA INDICATIONS

Diazepam is indicated for rectal administration in the management of selected, refractory, patients with epilepsy, on stable regimens of antiepileptic drugs, who require intermittent use of diazepam to control bouts of increased seizure activity.

DOSAGE AND ADMINISTRATION

- The Diastat dose should be individualized for maximum beneficial effect. The recommended dose of Diastat is 0.2-0.5mg/kg depending on age. See the dosing table for specific recommendations:
- Because Diastat is provided as unit doses of 2.5, 5, 7.5, 10, 12.5, 15, 17.5, and 20mg, the prescribed dose is obtained by rounding upward to the next available dose. The following table provides acceptable weight ranges for each dose and age category, such that patients will receive between 90% and 180% of the calculated recommended dose.

2-5 Years (0.5mg/kg)		6-11 Years (0.3mg/kg)		12+ Years (0.2mg/kg)	
Weight (kg)	Dose (mg)	Weight (kg)	Dose (mg)	Weight (kg)	Dose (mg)
6-10	5	10-16	5	14-25	5
11-15	7.5	17-25	7.5	26-37	7.5
16-20	10	26-33	10	38-50	10
21-25	12.5	34-41	12.5	51-62	12.5
26-30	15	42-50	15	63-75	15
31-35	17.5	51-58	17.5	76-87	17.5
36-44	20	59-74	20	88-111	20

- In elderly and debilitated patients, it is recommended that the dosage be adjusted downward to reduce the likelihood of ataxia or oversedation.
- The prescribed dose of Diastat should be adjusted by the physician periodically to reflect changes in the patient's age or weight.
- The Diastat 2.5mg dose may also be used as a partial replacement dose for patients who may expel a portion of the first dose.
- The prescriber may wish to prescribe a second dose of Diastat. A second dose, when required, may be given 4-12 hours after the first dose.
- It is recommended that Diastat be used to treat no more than five episodes per month and no more than one episode every five days.

REFERENCES

1. Diastat. Prescribing Information. Valeant Pharmaceuticals International. November 2006.
2. Facts and Comparisons, St. Louis, 2010 eFacts CliniSphere Version ISBN 1-57439-036-8.

Revision/Review Date: 2/2010

Associated Policy: Prior Authorization of Medications 236.200

NOTE: Pharmacist reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.

SELECT HEALTH PRIOR AUTHORIZATION CRITERIA

DOLOPHINE (methadone) Oral Concentrate: 10mg/1mL; Oral Solution: 5mg/5mL, 10mg/5mL; Soluble Tablet: 40mg; Tablet: 5mg, 10mg

STATUS Preferred

PA CRITERIA FOR APPROVAL

- Diagnosis of moderate to severe pain not responsive to non-narcotic analgesics.
- Methadone is being prescribed at an appropriate dosage, based on patient's relevant characteristics and previous drug therapies.

If the above conditions are met, the request will be approved with a 6 month duration; if the above conditions are not met, the request will be referred to a Pharmacist for medical necessity review.

FDA INDICATIONS

- For detoxification treatment of opioid addiction (heroin or other morphine-like drugs).
- For maintenance treatment of opioid addiction (heroin or other morphine-like drugs), in conjunction with appropriate social and medical services.
- Pain (except oral concentrate and tablets for suspension): For the treatment of moderate to severe pain not responsive to non-narcotic analgesics.

DOSAGE AND ADMINISTRATION

Pain:

- The oral concentrate and tablets for suspension are not indicated for pain.
- Optimal methadone initiation and dose titration strategies for the treatment of pain have not been determined. Published equianalgesic conversion ratios between methadone and other opioids are imprecise, providing at best only population averages that cannot be applied consistently to all patients. It should be noted that many commonly cited equianalgesic tables only present relative analgesic potencies of single opioid doses in nontolerant patients, thus greatly underestimating methadone's analgesic potency and its potential for adverse reactions in repeated dose settings. Regardless of the dose-determination strategy employed, methadone is most safely initiated and titrated using small initial doses and gradual dose adjustments.
- As with all opioid drugs, it is necessary to adjust the dosing regimen for each patient individually, taking into account the patient's prior analgesic treatment experience. The dosing recommendations should only be considered as suggested approaches to what is actually a series of clinical decisions over time in the management of the pain of each individual patient. Prescribers should always follow appropriate management principles of careful assessment and ongoing monitoring.
- In the selection of an initial dose of methadone, pay attention to:
 1. The total daily dose, potency, and specific characteristics of the opioid the patient had been taking previously, if any.
 2. The relative potency estimate used to calculate an equianalgesic starting methadone dose; in particular, whether it is intended for use in acute or chronic methadone dosing.
 3. The patient's degree of opioid tolerance.
 4. The age, general condition, and medical status of the patient.
 5. Concurrent medications, particularly other CNS and respiratory depressants.
 6. The type, severity, and expected duration of the patient's pain.
 7. The acceptable balance between pain control and adverse reactions.
- **Initial Dosage:** When oral methadone is used as the first analgesic in patients who are not already being treated with and tolerant to opioids, the usual methadone starting dose is 2.5 to 10mg every 8 to 12 hours, slowly titrated to effect. More frequent administration may be required during methadone initiation in order to maintain adequate analgesia, and extreme caution is necessary to avoid overdosage, taking into account methadone's long half-life.
- **Conversion:**
 - **Parenteral to Oral Methadone:** Conversion from parenteral to oral methadone should initially use a 1:2 dose ratio (eg, parenteral methadone 5mg to oral methadone 10mg).
 - **Switching from Other Chronic Opioids:**
 - Switching a patient from another chronically administered opioid to methadone requires caution because of the uncertainty of dose-conversion ratios and incomplete cross-tolerance. Deaths have occurred in opioid-tolerant patients during conversion to methadone.
 - Conversion ratios in many commonly used equianalgesic dosing tables do not apply in the setting of repeated methadone dosing. Although the onset and duration of analgesic action, as well as the analgesic potency of methadone and morphine, are similar with single-dose administration,

methadone's potency increases over time with repeated dosing. Furthermore, the conversion ratio between methadone and other opiates varies dramatically depending on baseline opiate (morphine equivalent) use.

- The morphine to methadone conversion scheme is derived from various consensus guidelines for converting chronic pain patients to methadone from morphine. Health care providers should consult published conversion guidelines to determine the equivalent morphine dose for patients converting from other opioids.

Oral Morphine to Oral Methadone Conversion for Chronic Administration	
Total Daily Baseline Oral Morphine Dose	Estimated Daily Oral Methadone Requirement as Percent of Total Daily Morphine Dose
<100mg	20-30%
100-300mg	10-20%
300-600mg	8-12%
600-1,000mg	5-10%
1,000mg	<5%

- The total daily methadone dose derived from the conversion table may then be divided to reflect the intended dosing schedule (eg, for administration every 8 hours, divide total daily dose by 3).
- Note: Equianalgesic methadone dosing varies not only among patients, but also within the same patient, depending on baseline morphine (or other opioid) dose. The conversion table has been included in order to illustrate this concept and to provide a safe starting point for opioid conversion. Methadone dosing should not be based solely on these tables. Methadone conversion and dose titration methods should always be individualized to account for the patient's achievement of adequate pain relief and balanced against tolerability of opioid adverse reactions. If a patient develops intolerable opioid-related adverse reactions, the methadone dose, or dosing interval, may need to be adjusted.
- **Usual Dosage:** 0.7mg/kg daily in divided doses every 4 to 6 hours, as needed.
- **Elderly:** Give methadone with caution and reduce the initial dose.
- **Renal Function Impairment:** Give methadone with caution and reduce the initial dose.
- **Hepatic Function Impairment:** Give methadone with caution and reduce the initial dose.
- **Pregnancy:** Methadone clearance may be increased during pregnancy. Several small studies have demonstrated significantly lower trough methadone plasma concentrations and shorter methadone half-lives in women during pregnancy compared with after delivery. During pregnancy, a woman's methadone dose may need to be increased or their dosing interval decreased. Use methadone in pregnancy only if the potential benefit justifies the potential risk to the fetus.

REFERENCES

1. Facts and Comparisons, St. Louis, 2010 eFacts CliniSphere Version ISBN 1-57439-036-8.

Revision/Review Date: 2/2010

Associated Policy: Prior Authorization of Medications 236.200

NOTE: Pharmacist reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.

SELECT HEALTH PRIOR AUTHORIZATION CRITERIA

ELIDEL (pimecrolimus) Cream: 1%

STATUS Non-Preferred

PA CRITERIA FOR APPROVAL

INITIAL PA:

- Diagnosis of mild to moderate atopic dermatitis.

AND

- Non-immunocompromised patient.

AND

- Patient 2 years of age or older.

AND

- Patient has not adequately responded to two different preferred prescription strength corticosteroid therapies in the last 8 weeks.

OR

- Physician provides valid rationale why corticosteroid therapy is inappropriate (ex., use on the face).

If the above conditions are met, the request will be approved with a 3 month duration; if the above conditions are not met, the request will be referred to a Pharmacist for medical necessity review.

RENEWAL PA:

- Diagnosis of mild to moderate atopic dermatitis.
- Non-immunocompromised patient.
- Patient 2 years of age or older.
- Documentation that patient has been re-examined by their health care provider and continuation of Elidel therapy is appropriate.

If the above conditions are met, the request will be approved with a 6 month duration; if the above conditions are not met, the request will be referred to a Pharmacist for medical necessity review.

FDA INDICATIONS

Mild to Moderate Atopic Dermatitis: Elidel Cream 1% is indicated as second-line therapy for the short-term and non-continuous chronic treatment of mild to moderate atopic dermatitis in non-immunocompromised adults and children 2 years of age and older, who have failed to respond adequately to other topical prescription treatments, or when those treatments are not advisable.

DOSAGE AND ADMINISTRATION

Apply a thin layer to the affected skin areas twice daily.

***Elidel should not be used with occlusive dressings.

***Stop using when signs and symptoms of atopic dermatitis resolve.

***If signs and symptoms persist beyond 6 weeks, patients should be re-examined by their health care provider to confirm diagnosis of atopic dermatitis.

***Continuous long-term use of topical calcineurin inhibitors, including Elidel should be avoided, and application should be limited to areas of involvement with atopic dermatitis.

REFERENCES

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Revision/Review Date: 2/2010

Associated Policy: Prior Authorization of Medications 236.200

NOTE: Pharmacist reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.

SELECT HEALTH PRIOR AUTHORIZATION CRITERIA

EXJADE (deferasirox) Tablet for Oral Suspension: 125mg, 250mg, 500mg

STATUS Non-Preferred

PA CRITERIA FOR APPROVAL

Pediatric Population:

- Patient must be 2-21 years of age.
- Diagnosis of chronic iron overload due to blood transfusions.
- Patient receiving blood transfusions on a regular basis/participating in blood transfusion program.
- Serum ferritin concentration is consistently >1000mcg/L. If the serum ferritin levels fall consistently below 500mcg/L, Exjade must be discontinued.
- Initial starting dose 20mg/kg/day. Maximum maintenance dose of 40mg/kg/day.

Adult Population:

- Patient must be >21 years of age.
- Diagnosis of chronic iron overload due to blood transfusions.
- Patient receiving blood transfusions on a regular basis/participating in blood transfusion program.
- Serum ferritin concentration is consistently >1000mcg/L. If the serum ferritin levels fall consistently below 500mcg/L, Exjade must be discontinued.
- Documentation patient is unable to use Desferal (deferoxamine) parenterally.
- Initial starting dose 20mg/kg/day. Maximum maintenance dose of 40mg/kg/day.

If all of the above conditions are met, the request will be approved with a 3 month duration. After 3 months, patient must be re-evaluated based on above criteria. If the above conditions are not met, the request will be referred to a Pharmacist for medical necessity review.

FDA INDICATION

For the treatment of chronic iron overload (transfusional hemosiderosis) due to blood transfusions in patients 2 years of age or older.

DOSAGE AND ADMINISTRATION

- The recommended initial starting dose of Exjade is 20mg/kg/day.
- Doses should be rounded to the nearest available tablet strength.
- Dose adjustments should be made in increments of 5-10mg/kg/day.
- The maximum dose of Exjade is 40mg/kg/day.
- Tablets must be dispersed in water, orange juice, or apple juice to form a suspension.
- Take Exjade at the same time each day on an empty stomach, 30 minutes before a meal.

Renal Dosage Adjustments

- Pediatrics: The dose should be reduced by 10mg/kg, if serum creatinine levels rise above the age-appropriate upper limit of normal at two consecutive visits.
- Adults: The daily dose should be reduced by 10mg/kg if a rise in serum creatinine of >33% above the average of the pretreatment measurement is seen at two consecutive visits, and cannot be attributed to other causes.

REFERENCES

1. Exjade. Prescribing Information. Novartis Pharmaceuticals Corporation. April 2009.
2. Facts and Comparisons, St. Louis, 2009 eFacts CliniSphere Version ISBN 1-57439-036-8.

Revision/Review Date: 8/2009

Associated Policy: Prior Authorization of Medications 236.200

NOTE: Pharmacist reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.

SELECT HEALTH PRIOR AUTHORIZATION CRITERIA

INTRANASAL CORTICOSTEROIDS

STATUS Preferred, Pays at Point-of-Sale

FLONASE (fluticasone) Nasal Suspension: 50mcg

NASAREL (flunisolide) Nasal Solution: 25mcg, 29mcg

NASONEX (mometasone) Nasal Suspension: 50mcg

STATUS Non-Preferred, Requires Prior Authorization

BECONASE AQ (beclomethasone) Nasal Suspension: 42mcg

NASACORT AQ (triamcinolone) Nasal Solution: 55mcg

OMNARIS (ciclesonide) Nasal Suspension: 50mcg

RHINOCORT AQUA (budesonide) Nasal Suspension: 32mcg

VERAMYST (fluticasone) Nasal Suspension: 27.5mcg

PA CRITERIA FOR APPROVAL

- Documented trial and failure or intolerance to two preferred products for at least 4 weeks (28 days) of therapy each.

If the above conditions are met, the request will be approved with a 12 month duration; if the above conditions are not met, the request will be referred to a Pharmacist for medical necessity review.

REFERENCES

1. Facts and Comparisons, St. Louis, 2009 eFacts CliniSphere Version ISBN 1-57439-036-8.
2. Flonase. Prescribing Information. GlaxoSmithKline. August 2007.
3. Nasonex. Prescribing Information. Schering. September 2005.
4. Beconase AQ. Prescribing Information. GlaxoSmithKline. April 2005.
5. Nasacort AQ. Prescribing Information. Sanofi-Aventis. September 2008.
6. Omnaris. Prescribing Information. Sepracor. November 2007.
7. Rhinocort Aqua. Prescribing Information. AstraZeneca. January 2005.
8. Veramyst. Prescribing Information. GlaxoSmithKline. July 2008.

Revision/Review Date: 8/2009

Associated Policy: Prior Authorization of Medications 236.200

NOTE: Pharmacist reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.

SELECT HEALTH PRIOR AUTHORIZATION CRITERIA

KYTRIL (granisetron) Tablet: 1mg; Oral Solution: 1mg/5mL

STATUS Non-Preferred

PA CRITERIA FOR APPROVAL

- Current treatment with emetogenic chemotherapy or radiation therapy.
- Documented trial and failure with therapeutic doses or intolerance to ondansetron.

If the above condition is met, the request will be approved with a quantity limit of 12 tablets/30 days or 60mL/30 days for the duration of the chemotherapy or radiation, not to exceed 3 months; if the above condition is not met, the request will be referred to a Pharmacist for medical necessity review. If the request is for a quantity greater than 12 tablets/30 days or 60mL/30 days, the request will be referred to a Pharmacist for medical necessity review.

FDA INDICATIONS

- The prevention of nausea and vomiting associated with initial and repeat courses of emetogenic cancer therapy, including high-dose cisplatin.
- Nausea and vomiting associated with radiation, including total body irradiation and fractionated abdominal radiation.

DOSAGE AND ADMINISTRATION

Emetogenic Chemotherapy:

- **Adults:** The recommended adult dosage of Kytril is 2mg once daily or mg twice daily. In the 2mg once daily regimen, two 1mg tablets or 10mL of Kytril Oral Solution (2 teaspoonfuls, equivalent to 2mg of Kytril) are given up to 1 hour before chemotherapy. In the 1mg twice daily regimen, the first 1mg tablet or one teaspoonful (5mL) of Kytril Oral Solution is given up to 1 hour before chemotherapy, and the second table or second teaspoonful (5mL) of Kytril Oral Solution, 12 hours after the first. Either regimen is administered only on the day(s) chemotherapy is given. Continued treatment, while not on chemotherapy, has not been found useful.
- **Use in the Elderly, Pediatric Patients, Renal Failure Patients, or Hepatically Impaired Patients:** No dosage adjustment is recommended.

Radiation (Either Total Body Irradiation or Fractionated Abdominal Radiation):

- **Adults:** The recommended adult dosage of oral Kytril is 2mg once daily. Two 1mg tablets or 10mL of Kytril Oral Solution (2 teaspoonfuls, equivalent to 2 mg of Kytril) are taken within 1 hour of radiation.
- **Pediatric Use:** There is no experience with oral Kytril in the prevention of radiation-induced nausea and vomiting in pediatric patients.
- **Use in the Elderly:** No dosage adjustment is recommended.

REFERENCES

1. Kytril. Prescribing Information. Roche Laboratories, Inc. October 2009.
2. Facts and Comparisons, St. Louis, 2010 eFacts CliniSphere Version ISBN 1-57439-036-8.
3. The National Comprehensive Cancer Network (NCCN) and The American Cancer Society (ACS). Nausea and Vomiting. Treatment Guidelines for Patients with Cancer. Version 1. January 2001.
4. Steiner M, Yorgason RZ, Vermeulen LC, Theisen J. Patient outcomes after therapeutic interchange of dolasteron for granisetron. Am J Health-Syst Pharm. 2003;60(10):1023-8.
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Revision/Review Date: 2/2010

Associated Policy: Prior Authorization of Medications 236.200

NOTE: Pharmacist reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.

SELECT HEALTH PRIOR AUTHORIZATION CRITERIA

LIDODERM (lidocaine) Patch: 5%

STATUS Non-Preferred

PA CRITERIA FOR APPROVAL

Postherpetic Neuralgia:

- Diagnosis of postherpetic neuralgia.
- Documented trial and failure or intolerance to gabapentin. Trial consists of a minimum of 30 days at a dose of at least 1800mg/day.

Neuropathic Pain Associated with Diabetic Peripheral Neuropathy:

- Diagnosis of neuropathic pain associated with diabetic peripheral neuropathy.
- Documented trial and failure or intolerance to gabapentin. Trial consists of a minimum of 30 days at a dose of at least 1800mg/day.
- Documented trial and failure or intolerance to Cymbalta. Trial consists of a minimum of 30 days at a dose of at least 60mg/day.

Chronic Back Pain:

- Diagnosis of chronic back pain.
- Document trial and failure or intolerance to 3 preferred alternatives. Trial of preferred alternatives consists of a minimum of 30 days of therapy each at a therapeutic dosage.

If the above conditions are met, the request will be approved with a 12 month duration; if the above conditions are not met, the request will be referred to a Pharmacist for medical necessity review.

FDA INDICATIONS

Lidoderm is indicated for relief of pain associated with postherpetic neuralgia. It should be applied only to intact skin.

DOSAGE AND ADMINISTRATION

Apply Lidoderm to intact skin to cover the most painful area. Apply up to three patches, only once for up to 12 hours within a 24-hour period. Patches may be cut into smaller sizes with scissors prior to removal of the release liner.

REFERENCES

1. Lidoderm. Prescribing Information. Endo Pharmaceuticals, Inc. February 2008.
2. Facts and Comparisons, St. Louis, 2010 eFacts CliniSphere Version ISBN 1-57439-036-8.
3. Galluzzi KE. Management strategies for herpes zoster and postherpetic neuralgia. J Am Osteopath Assoc. 2007 Mar;107(3 Suppl 1):S8-S13.
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Revision/Review Date: 2/2010

Associated Policy: Prior Authorization of Medications 236.200

NOTE: Pharmacist reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.

SELECT HEALTH PRIOR AUTHORIZATION CRITERIA

LIPITOR (atorvastatin) Tablet: 10mg, 20mg, 40mg

STATUS Non-Preferred

LIPITOR (atorvastatin) Tablet: 80mg

STATUS Preferred

PA CRITERIA FOR APPROVAL

Lipitor 10mg, 20mg, 40mg:

- Processes at the point-of-sale if there is a history of an HIV/AIDS medication filled in the last 60 days. Otherwise, these strengths of Lipitor are non-preferred.

Lipitor 80mg:

- Preferred, processes at the point-of-sale.

If the above conditions are met, the request will be approved with a 12 month duration; if the above conditions are not met, the request will be referred to a Pharmacist for medical necessity review.

FDA INDICATIONS

Prevention of Cardiovascular Disease:

In adult patients without clinically evident coronary heart disease, but with multiple risk factors for coronary heart disease such as age, smoking, hypertension, low HDL-C, or a family history of early coronary heart disease, Lipitor is indicated to:

- Reduce the risk of myocardial infarction.
- Reduce the risk of stroke.
- Reduce the risk for revascularization procedures and angina.

In patients with type 2 diabetes, and without clinically evident coronary heart disease, but with multiple risk factors for coronary heart disease such as retinopathy, albuminuria, smoking, or hypertension, Lipitor is indicated to:

- Reduce the risk of myocardial infarction.
- Reduce the risk of stroke

In patients with clinically evident coronary heart disease, Lipitor is indicated to:

- Reduce the risk of myocardial infarction.
- Reduce the risk of fatal and non-fatal stroke.
- Reduce the risk for revascularization procedures.
- Reduce the risk of hospitalization for CHF.
- Reduce the risk of angina.

Hypercholesterolemia:

- As an adjunct to diet to reduce elevated total-C, LDL-C, apo B, and TG levels and to increase HDL-C in patients with primary hypercholesterolemia (heterozygous familial and non-familial) and mixed dyslipidemia (Fredrickson Types IIa and IIb).
- As an adjunct to diet for the treatment of patients with elevated serum TG levels (Fredrickson Type IV).
- For the treatment of patients with primary dysbetalipoproteinemia (Fredrickson Type III) who do not respond adequately to diet.
- To reduce total-C and LDL-C in patients with homozygous familial hypercholesterolemia as an adjunct to other lipid-lowering treatments (eg, LDL apheresis) or if such treatments are unavailable.
- As an adjunct to diet to reduce total-C, LDL-C, and apo B levels in boys and postmenarchal girls, 10 to 17 years of age, with heterozygous familial hypercholesterolemia if after an adequate trial of diet therapy the following findings are present:
 - a. LDL-C remains > 190 mg/dLOR
 - b. LDL-C remains > 160 mg/dLAND
 - There is a positive family history of premature cardiovascular disease.OR
 - Two or more other CVD risk factors are present in the pediatric patient.

DOSAGE AND ADMINISTRATION

Hypercholesterolemia (Heterozygous Familial and Non-familial) and Mixed Dyslipidemia (Fredrickson Types IIa and IIb):

- The recommended starting dose of Lipitor is 10 or 20mg once daily. Patients who require a large reduction in LDL-C (more than 45%) may be started at 40 mg once daily. The dosage range of Lipitor is 10 to 80mg once daily. Lipitor can be administered as a single dose at any time of the day, with or without food. The starting dose and maintenance doses of Lipitor should be individualized according to patient characteristics such as goal of therapy and response. After initiation and/or upon titration of Lipitor, lipid levels should be analyzed within 2 to 4 weeks and dosage adjusted accordingly. Since the goal of treatment is to lower LDL-C, the NCEP recommends that LDL-C levels be used to initiate and assess treatment response. Only if LDL-C levels are not available, should total-C be used to monitor therapy.

Heterozygous Familial Hypercholesterolemia in Pediatric Patients (10-17 years of age):

- The recommended starting dose of Lipitor is 10mg/day; the maximum recommended dose is 20mg/day (doses greater than 20 mg have not been studied in this patient population). Doses should be individualized according to the recommended goal of therapy. Adjustments should be made at intervals of 4 weeks or more.

Homozygous Familial Hypercholesterolemia:

- The dosage of Lipitor in patients with homozygous FH is 10 to 80mg daily. Lipitor should be used as an adjunct to other lipid-lowering treatments (eg, LDL apheresis) in these patients or if such treatments are unavailable.

REFERENCES

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2. Lipitor. Prescribing Information. Pfizer, Inc. June 2009.

Revision/Review Date: 2/2010

Associated Policy: Prior Authorization of Medications 236.200

NOTE: Pharmacist reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.

SELECT HEALTH PRIOR AUTHORIZATION CRITERIA

LONG-ACTING ATTENTION-DEFICIT/HYPERACTIVITY DISORDER (ADHD) MEDICATIONS

STATUS Preferred

ADDERALL XR (amphetamine salts) Capsule: 5mg, 10mg, 15mg, 20mg, 25mg, 30mg

CONCERTA (methylphenidate) Tablet: 18mg, 27mg, 36mg, 54mg

DEXEDRINE SPANSULE (dextroamphetamine) Capsule: 5mg, 10mg, 15mg

FOCALIN XR (dexmethylphenidate) Capsule: 5mg, 10mg, 15mg, 20mg

RITALIN LA (methylphenidate) Capsule: 10mg, 20mg, 30mg, 40mg

VYVANSE (lisdexamfetamine) Capsule: 20mg, 30mg, 40mg, 50mg, 60mg, 70mg

STATUS Non-Preferred

DAYTRANA (methylphenidate) Patch: 10mg/9hrs, 15mg/9hrs, 20mg/9hrs, 30mg/9hrs

METADATE CD (methylphenidate) Capsule: 10mg, 20mg, 30mg, 40mg, 50mg, 60mg

PA CRITERIA FOR APPROVAL

- Preferred long-acting ADHD medications prescribed in a dose that exceeds FDA approved limits and/or Select Health daily quantity limits will require prior authorization.
- Requests will be considered base on the individual circumstances. Things that need to be considered include but are not limited to:
 - Previous therapy
 - Previous dose
 - Side effects of increased/higher once daily doses
 - Time of day initial dose wears off

If the above conditions are met, the request will be approved with a 12 month duration; if the above conditions are not met, the request will be referred to a Pharmacist for medical necessity review.

MAXIMUM DAILY DOSAGE & DAILY QUANTITY LIMITS

Drug	FDA Maximum Daily Dosage	Daily Quantity Limits
Adderall XR	30mg (ADHD) 60mg (Narcolepsy)	5mg, 10mg, 15mg: 1/day 20mg, 25mg, 30mg: 2/day
Concerta	72mg	18mg, 27mg, 54mg: 1/day 36mg: 2/day
Daytrana	30mg	All Strengths: 1/day
Dexedrine Spansule	40mg (ADHD) 60mg (Narcolepsy)	5mg: 2/day 10mg: 5/day 15mg: 4/day
Focalin XR	20mg	All Strengths: 1/day
Metadate CD	60mg	All Strengths: 1/day
Ritalin LA	60mg	10mg, 20mg, 40mg: 1/day 30mg: 2/day
Vyvanse	70mg	All Strengths: 1/day

REFERENCES

1. Facts and Comparisons, St. Louis, eFacts 2009 CliniSphere Version ISBN 1-57439-036-8.
2. Adderall XR. Prescribing Information. Shire. March 2009.
3. Concerta. Prescribing Information. McNeil. June 2009.
4. Daytrana. Prescribing Information. Shire. January 2008.
5. Dexedrine Spansule. Prescribing Information. GlaxoSmithKline. July 2008.
6. Focalin XR. Prescribing Information. Novartis. October 2008.
7. Metadate CD. Prescribing Information. UCB. February 2007.
8. Ritalin LA. Prescribing Information. Novartis. April 2009.
9. Vyvanse. Prescribing Information. Shire. May 2009.

Revision/Review Date: 8/2009

Associated Policy: Prior Authorization of Medications 236.200

NOTE: Pharmacist reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.

SELECT HEALTH PRIOR AUTHORIZATION CRITERIA

LYRICA (pregabalin) Capsule: 25mg, 50mg, 75mg, 100mg, 150mg, 200mg, 225mg, 300mg
STATUS Non-Preferred

PA CRITERIA FOR APPROVAL

Partial-Onset Seizures:

- Documented diagnosis of partial-onset seizures.
- Patient currently receiving another anticonvulsant medication at a therapeutic dosage.
- Documented trial and failure or intolerance to gabapentin.

If the above conditions are met, the request will be approved for a 12 month duration; if the above conditions are not met, the request will be to a Pharmacist for medical necessity review.

Postherpetic Neuralgia:

- Documented diagnosis of postherpetic neuralgia.
- Documented trial and failure or intolerance to gabapentin. Trial consists of a minimum of 30 days at a dose of at least 1800mg/day.

If the above conditions are met, the request will be approved for a 12 month duration; if the above conditions are not met, the request will be to a Pharmacist for medical necessity review.

Neuropathic Pain Associated with Diabetic Peripheral Neuropathy:

- Documented diagnosis of peripheral neuropathy.
- Documented trial and failure or intolerance to gabapentin. Trial consists of a minimum of 30 days at a dose of at least 1800mg/day.

If the above conditions are met, the request will be approved for a 12 month duration; if the above conditions are not met, the request will be to a Pharmacist for medical necessity review.

Fibromyalgia:

- Documented diagnosis of fibromyalgia.

If the above conditions are met, the request will be approved for a 12 month duration; if the above conditions are not met, the request will be to a Pharmacist for medical necessity review.

Trigeminal Neuralgia Pain:

- Documented diagnosis of trigeminal neuralgia.
- Documented trial and failure or intolerance to at least three of the following: baclofen, carbamazepine, gabapentin, lamotrigine, oxcarbazepine, phenytoin.

If the above conditions are met, the request will be approved for a 12 month duration; if the above conditions are not met, the request will be to a Pharmacist for medical necessity review.

FDA INDICATIONS

- Adjunctive therapy for adult patients with partial-onset seizures.
- Management of postherpetic neuralgia.
- Management of neuropathic pain associated with diabetic neuropathy.
- Management of fibromyalgia.

DOSAGE AND ADMINISTRATION

Partial-Onset Seizures:

Lyrica at doses of 150 to 600mg/day has been shown to be effective as adjunctive therapy in the treatment of partial onset seizures in adults. The total daily dose should be divided and given either two or three times daily. Both the efficacy and adverse event profiles of Lyrica have been shown to be dose related. In general, it is recommended that patients be started on a total daily dose no greater than 150mg/day (75mg two times a day, or 50mg three times a day). Based on individual patient response and tolerability, the dose may be increased to a maximum dose of 600mg/day. Because Lyrica is eliminated primarily by renal excretion, the dose should be adjusted for patients with reduced renal function. The effect of dose escalation rate on the tolerability of Lyrica has not been formally studied. The efficacy of add-on Lyrica in patients taking gabapentin has not been evaluated in controlled trials. Consequently, dosing recommendations for the use of Lyrica with gabapentin cannot be offered.

Postherpetic Neuralgia:

The recommended dose of Lyrica is 75 to 150mg two times a day, or 50 to 100mg three times a day (150 to 300mg/day) in patients with creatinine clearance of at least 60mL/min. Dosing should begin at 75mg two times a day, or 50mg three times a day (150mg/day) and may be increased to 300mg/day within 1 week based on efficacy and tolerability. Because Lyrica is eliminated primarily by renal excretion, the dose should be adjusted for patients with reduced renal function. Patients who do not experience sufficient pain relief following 2 to 4 weeks of treatment with 300mg/day, and who are able to tolerate Lyrica, may be treated with up to 300mg two times a day, or 200mg three times a day (600mg/day). In view of the dose-dependent adverse reactions and the higher rate of treatment discontinuation due to adverse reactions, dosing above 300mg/day should be reserved only for those patients who have on-going pain and are tolerating 300mg daily.

Neuropathic Pain Associated with Diabetic Peripheral Neuropathy:

The maximum recommended dose of Lyrica is 100mg three times a day (300mg/day) in patients with creatinine clearance of at least 60mL/min. Dosing should begin at 50 mg three times a day (150mg/day) and may be increased to 300mg/day within 1 week based on efficacy and tolerability. Because Lyrica is eliminated primarily by renal excretion, the dose should be adjusted for patients with reduced renal function. Although Lyrica was also studied at 600mg/day, there is no evidence that this dose confers additional significant benefit and this dose was less well tolerated. In view of the dose-dependent adverse reactions, treatment with doses above 300mg/day is not recommended.

Fibromyalgia:

The recommended dose of Lyrica for fibromyalgia is 300-450 mg/day. Dosing should begin at 75mg two times a day (150mg/day) and may be increased to 150mg two times a day (300mg/day) within 1 week based on efficacy and tolerability. Patients who do not experience sufficient benefit with 300mg/day may be further increased to 225mg two times a day (450mg/day). Although Lyrica was also studied at 600mg/day, there is no evidence that this dose confers additional benefit and this dose was less well tolerated. In view of the dose-dependent adverse reactions, treatment with doses above 450mg/day is not recommended. Because Lyrica is eliminated primarily by renal excretion, the dose should be adjusted for patients with reduced renal function.

Lyrica Dosage Based on Renal Function:

Creatinine Clearance (CrCl) (mL/min)	Total Lyrica Daily Dose (mg/day)*				Dose Regimen
	150	300	450	600	
≥60	150	300	450	600	BID or TID
30-60	75	150	225	300	BID or TID
15-30	25-50	75	110-150	150	QD or BID
<15	25	25-50	50-75	75	QD
Supplementary Dose Following Hemodialysis (mg)^					
Patients on the 25mg QD regimen: take one supplemental dose of 25mg or 50mg					
Patients on the 25-50mg QD regimen: take one supplemental dose of 50mg or 75mg					
Patients on the 50-75mg QD regimen: take one supplemental dose of 75mg or 100mg					
Patients on the 75mg QD regimen: take one supplemental dose of 100mg or 150mg					

TID= Three divided doses; BID= Two divided doses; QD= Single daily dose.

*Total daily dose (mg/day) should be divided as indicated by dose regimen to provide mg/dose.

^Supplementary dose is a single additional dose.

REFERENCES

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7. Goldenberg DL, Burckhardt C, Crofford L. Management of fibromyalgia syndrome. *JAMA*. 2004 Nov 17;292(19):2388-95.
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Revision/Review Date: 11/2009

Associated Policy: Prior Authorization of Medications 236.200

NOTE: Pharmacist reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.

SELECT HEALTH PRIOR AUTHORIZATION CRITERIA

MEPRON (atovaquone) Oral Suspension: 750mg/5mL

STATUS Preferred

PA CRITERIA FOR APPROVAL

- Diagnosis or need for prevention of Pneumocystis carinii pneumonia.
- Documented trial and failure with therapeutic doses or intolerance to trimethoprim-sulfamethoxazole (TMP-SMX).

If the above conditions are met, the request will be approved with a 12 month duration; if the above conditions are not met, the request will be referred to a Pharmacist for medical necessity review.

FDA INDICATIONS

- Mepron is indicated for the prevention of Pneumocystis carinii pneumonia in patients who are intolerant to TMP-SMX.
- Mepron is indicated for the acute oral treatment of mild-to-moderate PCP in patients who are intolerant to TMP-SMX.

DOSAGE AND ADMINISTRATION

Prevention of PCP (Patients 13 Years of Age and Older):

- The recommended dose is 1,500mg (10mL) once daily administered with a meal.

Treatment of Mild-to-Moderate PCP (Patients 13 Years of Age and Older):

- The recommended dose is 750mg (5mL) administered with meals twice daily for 21 days (total daily dose 1,500mg).

REFERENCES

1. Mepron. Prescribing Information. GlaxoSmithKline. May 2008.
2. Facts and Comparisons, St. Louis, 2010 eFacts CliniSphere Version ISBN 1-57439-036-8.
3. Kovacs JA, Gill VJ, Meshnick S, Masur H. New insights into transmission, diagnosis, and drug treatment of Pneumocystis carinii pneumonia. JAMA. 2001 Nov 21;286(19):2450-60.
4. Rosenberg DM, McCarthy W, Slavinsky J, Chan CK, Montaner J, Braun J, et al. Atovaquone suspension for treatment of Pneumocystis carinii pneumonia in HIV-infected patients. AIDS. 2001 Jan 26;15(2):211-4.
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Revision/Review Date: 2/2010

Associated Policy: Prior Authorization of Medications 236.200

NOTE: Pharmacist reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.

SELECT HEALTH PRIOR AUTHORIZATION CRITERIA

NON-PREFERRED MEDICATIONS

PA CRITERIA FOR APPROVAL

- Appropriate diagnosis/indication for requested non-preferred medication.
- Appropriate dose of medication based on age (i.e. pediatric and elderly populations) and indication.

And patient meets one of the three following criteria:

- Documented trial and failure or intolerance with up to three preferred medications used to treat the documented diagnosis. For medications where there is only one preferred agent, only that agent must have been ineffective or not tolerated.
- No other preferred medication has a medically accepted use for the patient's specific diagnosis as referenced in the medical compendia*.
- All other preferred medications are contraindicated based on the patient's diagnosis, other medical conditions, or other medication therapy.

If the above conditions are met, the request will be approved with up to a 12 month duration depending upon the diagnosis and usual treatment therapies; if the above conditions are not met, the request will be referred to a Pharmacist for medical necessity review.

*Medical compendia consists of the following: the Food and Drug Administration (FDA) approved indication(s) (Drug Package Insert), Micromedex, American Hospital Formulary Service (AHFS), and DrugPoints (formerly known as USPDI).

Revision/Review Date: 8/2009

Associated Policy: Prior Authorization of Medications 236.200

NOTE: Pharmacist reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.

SELECT HEALTH PRIOR AUTHORIZATION CRITERIA

OPHTHALMIC ANTIHISTAMINES

STATUS Preferred, Pays at Point-of-Sale (First Line)

ALAWAY OTC (ketotifen) Ophthalmic Solution: 0.025% (10mL)

CLARITIN EYE OTC (ketotifen) Ophthalmic Solution: 0.025% (5 mL)

ZADITOR OTC (ketotifen) Ophthalmic Solution: 0.025% (5mL)

ZYRTEC ITCHY EYE OTC (ketotifen) Ophthalmic Solution: 0.025% (5mL)

STATUS Preferred, Requires Step Therapy (Second Line)

PATADAY (olopatadine) Ophthalmic Solution: 0.2% (2.5mL)

PATANOL (olopatadine) Ophthalmic Solution: 0.1% (5mL)

NOTE: Patient must meet #1 criterion for approval of PA request.

STATUS Non-Preferred, Requires Prior Authorization (Third Line)

BEPREVE (bepotastine besilate) Ophthalmic Solution: 1.5% (10mL)

ELESTAT (epinastine) Ophthalmic Solution: 0.05% (5mL)

OPTIVAR (azelastine) Ophthalmic Solution: 0.05% (6mL)

NOTE: Patient must meet #1 & #2 criteria for approval of PA request.

PA CRITERIA FOR APPROVAL

1. Documented trial and failure or intolerance to Zaditor OTC, Alaway OTC, Claritin Eye OTC or Zyrtec Itchy Eye OTC (first line agents) for at least 2 weeks (14 days) of therapy.
2. Documented trial and failure or intolerance to Pataday or Patanol (second line agents) for at least 2 weeks (14 days) of therapy.

If the above conditions are met, the request will be approved with a 12 month duration; if the above conditions are not met, the request will be referred to a Pharmacist for medical necessity review.

FDA INDICATIONS

- **Alaway OTC:** For the temporary relief of itching of the eye due to ragweed, pollen, grass, animal hair and dander.
- **Claritin Eye OTC:** For the temporary relief of itchy eyes due to ragweed, pollen, grass, animal hair and dander.
- **Zaditor OTC:** For the temporary relief of itchy eyes due to ragweed, pollen, grass, animal hair and dander.
- **Zyrtec Itchy Eye OTC:** For the temporary relief of itchy eyes due to ragweed, pollen, grass, animal hair and dander.
- **Pataday:** For the treatment of ocular itching associated with allergic conjunctivitis.
- **Patanol:** For the treatment of the signs and symptoms of allergic conjunctivitis.
- **Bepreve:** For the treatment of itching associated with allergic conjunctivitis.
- **Elestat:** For the prevention of itching associated with allergic conjunctivitis.
- **Optivar:** Treatment of itching of the eye associated with allergic conjunctivitis.

NOTE: All of these agents are indicated for patients 3 years of age and older with the exception of Bepreve which is indicated for patients 2 years of age and older.

DOSAGE AND ADMINISTRATION

- **Alaway OTC:** Put 1 drop in the affected eye(s) twice daily, every 8-12 hours, no more than twice per day.
- **Claritin Eye OTC:** Put 1 drop in the affected eye(s) twice daily, every 8-12 hours, no more than twice per day.
- **Zaditor OTC:** Put 1 drop into each affected eye twice a day.
- **Zyrtec Itchy Eye OTC:** Put 1 drop in the affected eye twice daily, every 8-12 hours, no more than twice per day.
- **Pataday:** Put 1 drop into each affected eye once a daily.
- **Patanol:** Put 1 drop into each affected eye two times per day at an interval of 6-8 hours.
- **Bepreve:** Put 1 drop into the affected eye twice a day.
- **Elestat:** Put 1 drop in each eye twice daily. Treatment should be continued throughout the period of exposure, even when symptoms are absent.
- **Optivar:** Put 1 drop into each affected eye twice a day.

REFERENCES

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9. Optivar. Prescribing Information. Meda Pharmaceuticals. 2008.

Revision/Review Date: 2/2010

Associated Policy: Prior Authorization of Medications 236.200

NOTE: Pharmacist reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.

SELECT HEALTH STEP THERAPY CRITERIA

ORAL DIABETIC AGENTS

STATUS Preferred

ACTOS (pioglitazone) Tablet: 15mg, 30mg, 45mg

ACTOPLUS MET (metformin/pioglitazone) Tablet: 500mg/15mg, 850mg/15mg

AVANDAMET (metformin/rosiglitazone) Tablet: 500/2mg, 500/4mg, 1000/2mg, 1000/4mg

AVANDARYL (glimepiride/rosiglitazone) Tablet: 1/4mg, 2/4mg, 2/8mg, 4/4mg, 4/8mg

AVANDIA (rosiglitazone) Tablet: 2mg, 4mg, 8mg

DUETACT (glimepiride/pioglitazone) Tablet: 2mg/30mg, 4mg/30mg

GLYSET (miglitol) Tablet: 25mg, 50mg, 100mg

JANUMET (sitagliptin/metformin) Tablet: 50/500mg, 50/1000mg

JANUVIA (sitagliptin) Tablet: 25mg, 50mg, 100mg

ONGLYZA (saxagliptin) Tablet: 2.5mg, 5mg

PRECOSE (acarbose) Tablet: 25mg, 50mg, 100mg

STARLIX (nateglinide) Tablet: 60mg, 120mg

PA CRITERIA FOR APPROVAL

- Diagnosis of Type 2 diabetes mellitus.

AND

- Documented trial and failure with therapeutic doses, contraindication, or intolerance to at least one preferred sulfonylurea.

OR

- Documented trial and failure with therapeutic doses, contraindication, or intolerance to metformin.

If the above conditions are met, the request will be approved with a 12 month duration; if the above conditions are not met, the request will be referred to a Pharmacist for medical necessity review.

REFERENCES

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Revision/Review Date: 5/2010

Associated Policy: Prior Authorization of Medications 236.200

NOTE: Pharmacist reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.

SELECT HEALTH PRIOR AUTHORIZATION CRITERIA

OVIDE (malathion) Lotion: 0.5%
KWELL (lindane) Lotion: 1%, Shampoo: 1%
ULESFIA (benzyl alcohol) Lotion: 5%

STATUS Preferred
STATUS Preferred
STATUS Preferred

PA CRITERIA FOR APPROVAL

- Covered if first-line preferred agent (ex. Nix, Permethrin, Eurax) filled in the last 45 days.

If the above conditions are met, the request will be approved for a one-time fill with a quantity limit of no greater than 59mL (1 package) of Ovide, 60mL (1 package) of Lindane or 1,362mL (6 packages) of Ulesfia. If the above conditions are not met, the request will be referred to a Pharmacist for medical necessity review.

FDA INDICATIONS

Ovide:

Indicated for patients infected with *Pediculus humanus capitis* (head lice and their ova) of the scalp hair.

Kwell Lotion:

For the treatment of scabies (*Sarcoptes scabiei*) only in patients who cannot tolerate or who have failed other treatments.

Kwell Shampoo:

For the treatment of head lice (*Pediculosis humanis capitis*), crab lice (*Pthirus pubis*), and their ova only in patients who cannot tolerate or who have failed other treatments.

Ulesfia:

For the topical treatment of head lice infestation in patients 6 months of age and older. Ulesfia does not have ovicidal activity.

DOSAGE AND ADMINISTRATION

Ovide:

Apply Ovide on dry hair in amount just sufficient to thoroughly wet the hair and scalp. Pay particular attention to the back of the head and neck while applying Ovide. Wash hands after applying to scalp. Allow hair to dry naturally, use no electric heat source, and allow hair to remain uncovered. After 8-12 hours, the hair should be shampooed. Rinse and use a fine-toothed (nit) comb to remove dead lice and eggs. If lice are still present after 7-9 days, repeat with a second application of Ovide.

Kwell Lotion:

Apply a thin layer of lotion over all skin (ie, entire trunk, extremities, soles of feet, underneath finger nails) from the neck down. Wash hands immediately or use gloves when applying Lindane. One ounce (30mL) is sufficient for an average adult. Do not prescribe more than 2 ounces (60mL) for larger adults. Apply once and wash off in 8 to 12 hours. Do not retreat unless instructed to do so by a physician; 1 application of Lindane is generally successful. Do not cover areas where medication is applied. Treat sexual contacts concurrently. Patient may bathe prior to application; however, wait at least 1 hour after bathing before applying Lindane to skin. Wet and warm skin may increase absorption, leading to toxicity (eg, seizures).

Kwell Shampoo:

Apply shampoo directly to dry hair without adding water. Work thoroughly into the hair and allow to remain in place for 4 minutes only. Give special attention to the fine hairs along the neck. After 4 minutes, add small quantities of water to hair until a good lather forms. Immediately rinse all lather away. Towel briskly and then remove nits with nit comb or tweezers. Do not cover the hair with shower cap or towel. Avoid unnecessary contact of lather with other body surfaces. Do not prescribe more than 2 ounces (60mL) for larger adults. Do not retreat or use as a routine shampoo. Treat sexual contacts concurrently.

Ulesfia:

Using the guidelines below, apply sufficient Ulesfia lotion to dry hair to completely saturate the scalp and hair. Leave on for 10 minutes then thoroughly rinse off with water. Repeat treatment after 7 days to get rid of lice that hatched from eggs.

Hair Length (inches)		Amount of Ulesfia Lotion Per Treatment
Short	0-2	4-6 oz (1/2 – 3/4 bottle)
	2-4	6-8 oz (3/4 – 1 bottle)
Medium	4-8	8-12 oz (1 – 1&1/2 bottles)
	8-16	12-24 oz (1&1/2 – 3 bottles)
Long	16-22	24-32 oz (3 – 4 bottles)
	Over 22	32-48 oz (4 – 6 bottles)

REFERENCES

1. Ovide. Prescribing Information. TaroPharma. July 2005.
2. Facts and Comparisons, St. Louis, 2009 eFacts CliniSphere Version ISBN 1-57439-036-8.
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4. Frankowski, BL. American academy of pediatrics guidelines for the prevention and treatment of head lice infestation. Am J Manage Care. 2004;10(9):S269-S272.
5. Meinking TL. Clinical update on resistance and treatment of pediculosis capitis. Am J Manage Care. 2004;10:S264-S268.
6. Lindane Prescribing Information. Morton Grove Pharmaceuticals Inc. June 2005.
7. Ulesfia Prescribing Information. Sciele Pharma, Inc. April 2009.

Revision/Review Date: 11/2009

Associated Policy: Prior Authorization of Medications 236.200

NOTE: Pharmacist reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.

SELECT HEALTH PRIOR AUTHORIZATION CRITERIA

OXYCONTIN (oxycodone extended-release) Tablet: 10mg, 15mg, 20mg, 30mg, 40mg, 60mg, 80mg

STATUS Non-Preferred

PA CRITERIA FOR APPROVAL

- Diagnosis of chronic pain requiring an opioid analgesic.
- Documented trial and failure at therapeutic maximum doses or intolerance to sustained release morphine sulfate.
- Documented trial and failure at therapeutic maximum doses or intolerance to fentanyl.

If the above conditions are met, the request will be approved with a 6 month duration; if the above conditions are not met, the request will be referred to a Pharmacist for medical necessity review.

FDA INDICATIONS

- Management of moderate-to-severe pain when a continuous, around-the-clock analgesic is needed for an extended period of time.
- Not intended for use as a “prn” analgesic.

DOSAGE AND ADMINISTRATION

Initiate the dosing regimen for each patient individually, taking into account the patient's prior opioid and non-opioid treatment. OxyContin 60mg and 80mg tablets, or a single dose greater than 40mg, are for use in opioid-tolerant patients only. Attention should be given to:

- The general condition and medical status of the patient
- The patient's opioid exposure and opioid tolerance (if any)
- The daily dose, potency, and kind of analgesic(s) the patient has been taking
- The reliability of the conversion estimate used to calculate the dose of OxyContin
- Special safety issues associated with conversion to OxyContin doses at or exceeding 160mg every 12 hours
- The balance between pain control and adverse experiences

Care should be taken to use low initial doses of OxyContin who are not already opioid-tolerant, especially those who are receiving concurrent treatment with muscle relaxants, sedatives, or other CNS active medications. Experience indicates a reasonable starting dose of OxyContin for patients who are taking non-opioid analgesic and require continuous around-the-clock therapy for an extended period of time is 10mg every 12 hours. OxyContin should be individually titrated to a dose that provides adequate analgesia and minimizes side effects.

REFERENCES

1. OxyContin. Prescribing Information. Purdue Pharma. September 2009.
2. Facts and Comparisons, St. Louis, 2010 eFacts CliniSphere Version ISBN 1-57439-036-8.
3. American Cancer Society (ACS). National Comprehensive Cancer Network (NCCN). Cancer Pain. Treatment Guidelines for Patients. Version 1. January 2001.
4. World Health Organization. Geneva. 1996. Cancer Pain Relief. Second Edition. With a guide to Opioid Availability.
5. Stambaugh JE, et al. Double-blind, randomized comparison of the analgesic and pharmacokinetic profiles of controlled- and immediate-release oral oxycodone in cancer pain patients. J Clin Pharmacol 2001 May;41(5):500-6.
6. Neighbors DM, et al. Economic evaluation of the fentanyl transdermal system for the treatment of chronic moderate to severe pain. J Pain Symptom Manage 2001 Feb;21(2):129-43.
7. Mucci-LoRusso P, et al. Controlled-release oxycodone compared with controlled-release morphine in the treatment of cancer pain: a randomized, double-blind, parallel-group study. Eur J Pain 1998;2(2):239-249.

Revision/Review Date: 2/2010

Associated Policy: Prior Authorization of Medications 236.200

NOTE: Pharmacist reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.

SELECT HEALTH PRIOR AUTHORIZATION CRITERIA

PONSTEL (mefenamic acid) Capsule: 250mg

STATUS Non-Preferred

PA CRITERIA FOR APPROVAL

- Diagnosis of acute, mild-to-moderate pain or primary dysmenorrhea.

AND

- Documented trial and failure with therapeutic prescription doses or intolerance to at least three preferred NSAIDs for at least 2 weeks (14 days) of duration for each NSAID.

OR

- Documented trial and failure with therapeutic doses or intolerance to Celebrex.

If the above conditions are met, the request will be approved with a 1 month duration; if the above conditions are not met, the request will be referred to a Pharmacist for medical necessity review.

FDA INDICATIONS

- For relief of mild-to-moderate pain in patients 14 years of age and older, when therapy will not exceed one week (7 days).
- For treatment of primary dysmenorrhea.

DOSAGE AND ADMINISTRATION

- **Relief of mild-to-moderate pain in patients 14 years of age and older:** The recommended dose is 500mg as an initial dose, followed by 250mg every 6 hours as needed, usually not to exceed one week.
- **Treatment of primary dysmenorrhea:** 500mg as an initial dose, followed by 250mg every 6 hours, starting with the onset of bleeding and associated symptoms. Clinical studies indicated that effect treatment can be initiated with the start of menses and should not be necessary for more than 2-3 days.

REFERENCES

1. Ponstel. Prescribing Information. Sciele Pharma, Inc. February 2009.
2. Facts and Comparisons, St. Louis, 2010 eFacts CliniSphere Version ISBN 1-57439-036-8.

Revision/Review Date: 2/2010

Associated Policy: Prior Authorization of Medications 236.200

NOTE: Pharmacist reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.

SELECT HEALTH PRIOR AUTHORIZATION CRITERIA

PROTON PUMP INHIBITORS (PPIs)

STATUS Preferred, Pays at Point-of-Sale (First Line)

OMEPRAZOLE OTC (omeprazole) Tablet: 20mg

PREVACID (lansoprazole) SoluTab: 15mg, 30mg (Patients 9 years of age and younger)

PRILOSEC OTC (omeprazole) Tablet: 20mg

PRILOSEC RX (omeprazole) Capsule: 10mg, 20mg, 40mg

STATUS Preferred, Requires Step Therapy (Second Line)

DEXILANT (formerly known as KAPIDEX) (dexlansoprazole) Capsule: 30mg, 60mg

PREVACID (lansoprazole) Capsule: 15mg, 30mg

PREVACID 24HR OTC (lansoprazole) Capsule: 15mg

PREVACID (lansoprazole) SoluTab: 15mg, 30mg (Patients 10 years of age and older)

PROTONIX (pantoprazole) Tablet: 20mg, 40mg

PROTONIX (pantoprazole) Packet for Oral Suspension: 40mg (Children 9 years of age and younger)

NOTE: Patient must meet #1 & #2 criteria for approval of initial PA request.

STATUS Non-Preferred, Requires Prior Authorization (Third Line)

ACIPHEX (rabeprazole) Tablet: 20mg

NEXIUM (esomeprazole) Capsule: 20mg, 40mg; Packet for Oral Suspension: 10mg, 20mg, 40mg

PRILOSEC RX (omeprazole) Packet for Oral Suspension: 2.5mg, 10mg

PROTONIX (pantoprazole) Packet for Oral Suspension: 40mg (Patients 10 years of age and older)

ZEGERID (omeprazole/sodium bicarbonate) Capsule: 20mg/1100mg, 40mg/1100mg; Packet for Oral Suspension: 20mg/1680mg, 40mg/1680mg

NOTE: Patient must meet #1, #2, & #3 criteria for approval of initial PA request.

PA CRITERIA FOR APPROVAL

1. Presumed or documented diagnosis of duodenal ulcer, H.pylori, gastric ulcer, GERD, erosive esophagitis, or hypersecretory disease.
2. Documented trial and failure or intolerance with Prilosec OTC, Omeprazole OTC, or Omeprazole Rx for a minimum of 3 weeks of therapy within the previous 60 days **OR** request from a gastroenterologist or otolaryngologist.
3. Documented trial and failure or intolerance with Prevacid (lansoprazole) capsule, SoluTab or 24HR OTC 30mg once daily, Dexilant 30mg once daily and Protonix (pantoprazole) 40mg once daily for a minimum of 3 weeks of therapy each.

If the above conditions are met, the request will be approved with a 12 month duration; if the above conditions are not met, the request will be referred to a Pharmacist for medical necessity review.

Doses Greater Than Once Daily After Meeting Criteria for PPI:

- Confirmed diagnosis of GERD, erosive esophagitis, or hypersecretory disease.

OR

- Evaluation made by a gastroenterologist or otolaryngologist recommending higher doses of PPI.

If the above conditions are met, the request will be approved with a 12 month duration; if the above conditions are not met, the request will be referred to a Pharmacist for medical necessity review.

REFERENCES

1. Facts and Comparisons, St. Louis, 2010 eFacts CliniSphere Version ISBN 1-57439-036-8.
2. Aciphex. Prescribing Information. Eisai Co. January 2009.
3. Kapidex. Prescribing Information. Takeda Pharmaceuticals. August 2009.
4. Nexium. Prescribing Information. AstraZeneca. June 2009.
5. Prevacid. Prescribing Information. Takeda Pharmaceuticals. July 2009.
6. Prevacid 24HR. Available at: <http://www.prevacid24hr.com/index.jsp>. Accessed January 2010.
7. Protonix. Prescribing Information. Wyeth Pharmaceuticals. May 2008.
8. Prilosec. Prescribing Information. AstraZeneca. May 2008.
9. Prilosec OTC. Available from: <http://www.prilosecotc.com/>. Accessed January 2010.
10. Zegerid. Prescribing Information. Santarus. January 2008.
11. Juurlink DN, Gomes T, Ko DT, et al. A population-based study of the drug interaction between proton pump inhibitors and clopidogrel. CMAJ 2009; DOI:10.1503/cmaj.082001. Available at: <http://www.cmaj.ca>.
12. Ho PM, Maddox TM, Wang L, et al. Risk of adverse outcomes associated with concomitant use of clopidogrel and proton pump inhibitors following acute coronary syndrome. JAMA 2009;301:937-44.

13. Comparison of proton pump inhibitors. Pharmacist's Letter/Prescriber's Letter 2009;25(3):250304.
14. Siller-Matula JM, Spiel AO, Lang IM, et al. Effects of Pantoprazole and Esomeprazole on Platelet Inhibition by Clopidogrel. Am Heart J. 2009;157(1):148.
15. Proton pump inhibitor and Plavix interaction: does it exist? Pharmacist's Letter/Prescriber's Letter 2009;25(4):250401.
16. Proton pump inhibitor and Plavix interaction: an update. Pharmacist's Letter/Prescriber's Letter 2009;25(7):250706.

Revision/Review Date: 2/2010

Associated Policy: Prior Authorization of Medications 236.200

NOTE: Pharmacist reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.

SELECT HEALTH PRIOR AUTHORIZATION CRITERIA

PROTOPIC (tacrolimus) Ointment: 0.03%, 0.1%

STATUS Non-Preferred

PA CRITERIA FOR APPROVAL

INITIAL PA:

- Diagnosis of moderate to severe atopic dermatitis.

AND

- Non-immunocompromised patient.

AND

- Patient 2 years of age or older.

AND

- Patient has not adequately responded to two different preferred prescription strength corticosteroid therapies in the last 8 weeks.

OR

- Physician provides valid rationale why corticosteroid therapy is inappropriate (ex., use on the face).

If the above conditions are met, the request will be approved with a 3 month duration; if the above conditions are not met, the request will be referred to a Pharmacist for medical necessity review.

RENEWAL PA:

- Diagnosis of moderate to severe atopic dermatitis.
- Non-immunocompromised patient.
- Patient 2 years of age or older.
- Documentation that patient has been re-examined by their health care provider and continuation of Protopic therapy is appropriate.

If the above conditions are met, the request will be approved with a 6 month duration; if the above conditions are not met, the request will be referred to a Pharmacist for medical necessity review.

FDA INDICATIONS

Moderate to Severe Atopic Dermatitis: Protopic Ointment, both 0.03% and 0.1% for adults, and only 0.03% for children aged 2 to 15 years, is indicated as second-line therapy for the short-term and non-continuous chronic treatment of moderate to severe atopic dermatitis in non-immunocompromised adults and children who have failed to respond adequately to other topical prescription treatments for atopic dermatitis, or when those treatments are not advisable.

DOSAGE AND ADMINISTRATION

- **Adults (0.03% and 0.1%):** Apply a thin layer to the affected skin areas twice daily and rub in gently and completely.
- **Children 2-15 Years (0.03%):** Apply a thin layer to the affected skin areas twice daily and rub in gently and completely.

***Protopic should not be used with occlusive dressings.

***Stop using when signs and symptoms of atopic dermatitis resolve.

***If signs and symptoms persist beyond 6 weeks, patients should be re-examined by their health care provider to confirm diagnosis of atopic dermatitis.

***Continuous long-term use of topical calcineurin inhibitors, including Protopic should be avoided, and application should be limited to areas of involvement with atopic dermatitis.

REFERENCES

1. Protopic. Prescribing Information. Astellas Pharma US, Inc. June 2009.
2. Hanifin JM, Cooper KD, Ho VC, Kang S, et al. Guidelines of care for atopic dermatitis. J Am Acad Dermatol 2004;50(3):485-6.
3. Russell JJ. Topical tacrolimus: a new therapy for atopic dermatitis. Am Fam Physician, Nov 15 2002;66(10):1899-902.
4. Bergman J, Rico MJ. Tacrolimus clinical studies for atopic dermatitis and other conditions. Semin Cutan Med Surg, Dec 2001;20(4):250-9.
5. Reitamo S, Harper J, Bos JD, et al. 0.03% Tacrolimus ointment applied once or twice daily is more efficacious than 1% hydrocortisone acetate in children with moderate to severe atopic dermatitis: results of a randomized double blind controlled trial. Br J Dermatol. Mar 2004;150(3):554-62.

Revision/Review Date: 2/2010

Associated Policy: Prior Authorization of Medications 236.200

NOTE: Pharmacist reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.

SELECT HEALTH PRIOR AUTHORIZATION CRITERIA

PULMICORT RESPULES (budesonide) Inhalation Suspension: 0.25mg/2mL, 0.5mg/2mL, 1mg/2mL
STATUS Preferred

PA CRITERIA FOR APPROVAL

- Diagnosis of chronic asthma for patients 8 years of age and younger will process at the point-of-sale without prior authorization required if dosed within appropriate dosing guidelines as follows:
 - 0.25mg/2mL once daily
 - 0.5mg/2mL once daily or twice daily
 - 1mg/2mL once daily or twice daily
- A dose of 0.25mg/2mL twice daily will be approved if prescriber indicates that once daily dosing is not efficacious and determines that increasing the dose (i.e. 0.5mg once daily) is not appropriate for the patient.

If the above conditions are met, the request will be approved with a 12 month duration; if the above conditions are not met, the request will be referred to a Pharmacist for medical necessity review.

FDA INDICATIONS

- Pulmicort Respules is indicated for the maintenance treatment of asthma and as prophylactic therapy in children 12 months to 8 years of age.

DOSAGE AND ADMINISTRATION

Pulmicort Respules should be administered by the inhaled route via jet nebulizer connected to an air compressor. Individual patients will experience a variable onset and degree of symptom relief. Improvement in asthma control following inhaled administration of Pulmicort Respules can occur within 2-8 days of initiation of treatment, although maximum benefit may not be achieved for 4-6 weeks. The safety and efficacy of Pulmicort Respules when administered in excess of recommended doses have not been established. In all patients, it is desirable to downward-titrate to the lowest effective dose once asthma stability is achieved. The recommended starting dose and highest recommended dose of Pulmicort Respules, based on prior asthma therapy, are in the following table.

Previous Therapy	Recommended Starting Dose	Highest Recommended Dose
Bronchodilators alone	0.5mg total daily dose administered either once daily or twice daily in divided doses	0.5mg total daily dose
Inhaled Corticosteroids	0.5mg total daily dose administered either once daily or twice daily in divided doses	1mg total daily dose
Oral Corticosteroids	1mg total daily dose administered either as 0.5mg twice daily or 1mg once daily	1mg total daily dose

In symptomatic children not responding to non-steroidal therapy, a starting dose of 0.25mg once daily of Pulmicort Respules may also be considered. If once-daily treatment with Pulmicort Respules does not provide adequate control of asthma symptoms, the total daily dose should be increased and/or administered as a divided dose.

REFERENCES

1. Pulmicort Respules. Prescribing Information. Astra Zeneca. May 2009.
2. Facts and Comparisons, St. Louis, 2010 eFacts CliniSphere Version ISBN 1-57439-036-8.
3. Leflein JG, Gawchik SM, Galant SP, Lyzell E, Young M, Cruz-Rivera M, et al. Safety of budesonide inhalation suspension after up to 52 weeks of treatment in infants and young children with persistent asthma. Allergy Asthma Proc. 2001 Nov-Dec;22(6):359-66.
4. National Asthma Education and Prevention Program Clinical Practice Guidelines: Expert Panel Report 3: Guidelines for the Diagnosis and Management of Asthma: National Institutes of Health. National Heart, Lung and Blood Institute. NIH Publication No. 08-405. Prepublication Copy. Available at: <http://www.nhlbi.nih.gov/guidelines/asthma/asthgdln.pdf>.

Revision/Review Date: 2/2010

Associated Policy: Prior Authorization of Medications 236.200

NOTE: Pharmacist reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.

SELECT HEALTH PRIOR AUTHORIZATION CRITERIA

QUALAQUIN (quinine sulfate) Capsule: 324mg

STATUS Non-Preferred

PA CRITERIA FOR APPROVAL

- Diagnosis of uncomplicated Plasmodium falciparum malaria.

NOTE: Quaalquin will not be approved for the treatment or prevention of nocturnal leg clamps.

NOTE: Quaalquin will not be approved for the prevention of malaria.

If the above conditions are met, the request will be approved for a 7 day duration; if the above conditions are not met, the request will be referred to a Pharmacist for medical necessity review.

FDA INDICATION

For treatment of uncomplicated Plasmodium falciparum malaria in adults.

DOSAGE AND ADMINISTRATION

Dosage is 648mg (2 capsules) every 8 hours for 7 days.

REFERENCES

1. Facts and Comparisons, St. Louis, 2010 eFacts CliniSphere Version ISBN 1-57439-036-8.
2. Drugs.com. Quaalquin Drug Information Online. Available from: <http://www.drugs.com/pro/qualaquin.html>. Accessed August 2007.
3. Quaalquin. Prescribing Information. Mutual Pharmaceutical Co., Inc. November 2009.
4. FDA News. FDA Advances Effort Against Marketed Unapproved Drugs. Available from: <http://www.fda.gov/bbs/topics/NEWS/2006/NEW01521.html>. Accessed August 2007.

Revision/Review Date: 2/2010

Associated Policy: Prior Authorization of Medications 236.200

NOTE: Pharmacist reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.

SELECT HEALTH PRIOR AUTHORIZATION CRITERIA

RESTASIS (cyclosporine) Ophthalmic Emulsion: 0.05%

STATUS Preferred

PA CRITERIA FOR APPROVAL

- Diagnosis of dry eye syndrome (decreased tear production) whose lack of tear production is presumed to be suppressed due to ocular inflammation associated with keratoconjunctivitis sicca.
- Diagnosis and prescription by an ophthalmologist or rheumatologist.
- Documented trial and failure or intolerance to a therapeutic trial of artificial tear therapy for a period of 3 months.

If the above conditions are met, the request will be approved with a 12 month duration; if the above conditions are not met, the request will be referred to a Pharmacist for medical necessity review.

FDA INDICATIONS

Restasis is indicated to increase tear production in patients whose tear production presumed to be suppressed because of ocular inflammation associated with keratoconjunctivitis sicca.

DOSAGE AND ADMINISTRATION

Invert the unit dose vial a few times to obtain a uniform, white, opaque emulsion before using. Instill one drop of Restasis ophthalmic emulsion twice a day in each eye approximately 12 hours apart. Restasis can be used concomitantly with artificial tears, allowing a 15 minute interval between products. Discard vial immediately after use.

REFERENCES

1. Restasis. Prescribing Information. Allergan. January 2009.
2. Facts and Comparisons, St. Louis, 2010 eFacts CliniSphere Version ISBN 1-57439-036-8.
3. Pflugfelder SC. Anti-inflammatory Therapy of Dry Eye. *The Ocular Surface*; 2003;1:31-6.
4. Akpek EK, et al. A randomized trial of topical cyclosporine 0.05% in topical steroid resistant atopic keratoconjunctivitis. *Ophthalmology*. 2004;111(3):476-82.
5. Kunert KS, et al. Analysis of Topical Cyclosporine Treatment of Patients with Dry Eye Syndrome. *Arch Ophthalmol*. 2000;118:1489-96.

Revision/Review Date: 2/2010

Associated Policy: Prior Authorization of Medications 236.200

NOTE: Pharmacist reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.

SELECT HEALTH PRIOR AUTHORIZATION CRITERIA

REVIA (naltrexone) Tablet: 50mg

STATUS Preferred

PA CRITERIA FOR APPROVAL

- Diagnosis of alcoholism or narcotic dependence.

If the above conditions are met, the request will be approved with a 6 month duration; if the above conditions are not met, the request will be referred to a Pharmacist for medical necessity review.

FDA INDICATIONS

- ***Alcoholism***: Treatment of alcohol dependence.
- ***Narcotic Dependence***: Blockade of the effects of exogenously administered opioids.

DOSAGE AND ADMINISTRATION

Alcoholism:

A dose of 50mg once daily is recommended for most patients for up to 12 weeks.

Narcotic Dependence:

Initiate treatment using the following guidelines:

- Do not attempt treatment until the patient has remained opioid-free for 7 to 10 days. Verify by analyzing urine for opioids. The patient should not be manifesting withdrawal signs or reporting withdrawal symptoms.
- Administer a naloxone challenge test. If signs of opioid withdrawal are still observed following challenge, do not treat with naltrexone. The naloxone challenge can be repeated in 24 hours.
- Initiate treatment carefully, slowly increasing the dose. Administer 25mg initially; observe patient for 1 hour. If no withdrawal signs occur, give the rest of the daily dose.

Maintenance treatment: Once patient has started naltrexone, 50mg every 24 hours will produce adequate clinical blockade of the actions of parenterally administered opioids (ie, this dose will block the effects of a 25mg IV heroin challenge). Flexible dosing may be used. Thus, patients may receive 50mg every weekday with a 100mg dose on Saturday, 100mg every other day, or 150mg every third day. While the degree of opioid blockade may be somewhat reduced by using higher doses at longer dosing intervals, improved patient compliance may result from dosing every 48 to 72 hours. Several studies have employed the following dosing regimen with success: 100mg Monday, 100mg Wednesday and 150mg Friday.

REFERENCES

1. Revia (naltrexone). Prescribing Information. DuPont Pharmaceuticals. May 1999.
2. Naltrexone. Prescribing Information. Mallinckrodt Inc. February 2009.
3. Facts and Comparisons, St. Louis, 2010 eFacts CliniSphere Version ISBN 1-57439-036-8.
4. Graham R; Wodak AD; Whelan G. New pharmacotherapies for alcohol dependence. Med J Aust. 2002 Jul 15;177(2):103-7.
5. Latt NC; Jurd S; Houseman J; Wutzke SE. Naltrexone in alcohol dependence: a randomised controlled trial of effectiveness in a standard clinical setting. Med J Aust. 2002 Jun 3;176(11):530-4.
6. Volpicelli JR, Alterman M, Hayashida M, O'Brian CP. Naltrexone in the treatment of alcohol dependence. Arch Gen Psychiatry. 1992;49:876-80.

Revision/Review Date: 2/2010

Associated Policy: Prior Authorization of Medications 236.200

NOTE: Pharmacist reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.

SELECT HEALTH PRIOR AUTHORIZATION CRITERIA

SECOND GENERATION ANTIHISTAMINES

STATUS Preferred, Pays at Point-of-Sale (First Line)

CLARITIN (loratadine) Tablet: 10mg; RediTab: 10mg; Syrup: 5mg/5mL

CLARITIN-D 12 HOUR (loratadine/pseudoephedrine) Tablet: 5mg/120mg

CLARITIN-D 24 HOUR (loratadine/pseudoephedrine) Tablet: 10mg/240mg

ZYRTEC (cetirizine) Tablet: 5mg, 10mg; Chewable Tablet: 5mg, 10mg; Syrup: 5mg/5mL

ZYRTEC-D 12 HOUR (cetirizine/pseudoephedrine) Tablet: 5mg/120mg

STATUS Preferred, Requires Step Therapy (Second Line)

ALLEGRA (fexofenadine) Tablet: 30mg, 60mg, 180mg; Oral Suspension: 30mg/5mL

ALLEGRA-D 12 HOUR (fexofenadine/pseudoephedrine) Tablet: 60mg/120mg

ALLEGRA-D 24 HOUR (fexofenadine/pseudoephedrine) Tablet: 180mg/240mg

NOTE: Patient must meet #1 criterion for approval of PA request.

STATUS Non-Preferred, Requires Prior Authorization (Third Line)

ALLEGRA (fexofenadine) Orally Disintegrating Tablet: 30mg

CLARINEX (desloratadine) Tablet: 5mg; RediTab: 2.5mg, 5mg; Syrup: 2.5mg/5mL

CLARINEX-D 12 HOUR (desloratadine/pseudoephedrine) Tablet: 2.5mg/120mg

CLARINEX-D 24 HOUR (desloratadine/pseudoephedrine) Tablet: 5mg/240mg

XYZAL (levocetirizine) Tablet: 5mg; Oral Solution: 2.5mg/5mL

NOTE: Patient must meet #1 & #2 criteria for approval of PA request.

PA CRITERIA FOR APPROVAL

1. Documented trial and failure or intolerance to a preferred loratadine and cetirizine (first line) product for at least 2 weeks (14 days) of therapy each in the past 90 days.
2. Documented trial and failure or intolerance to a preferred fexofenadine (second line) product for at least 2 weeks (14 days) of therapy in the past 90 days.

If the above conditions are met, the request will be approved with a 12 month duration; if the above conditions are not met, the request will be referred to a Pharmacist for medical necessity review.

FDA INDICATIONS

ANTIHISTAMINES

Indications	Allegra	Clarinet	Claritin	Xyzal	Zyrtec
Seasonal Allergic Rhinitis	X	X	X	X	X
Perennial Allergic Rhinitis		X	X	X	X
Chronic Idiopathic Urticaria	X	X	X	X	X

COMBINATION ANTIHISTAMINES-DECONGESTANTS

Indications	Allegra-D 12 & 24 Hour	Clarinet-D 12 & 24 Hour	Claritin-D 12 & 24 Hour	Zyrtec-D 12 Hour
Seasonal Allergic Rhinitis	X	X	X	X
Perennial Allergic Rhinitis				X

DOSAGE AND ADMINISTRATION

Allegra

- Children 6-11 Years: 30mg twice daily.
- Adults and Children 12 Years and Older: 60mg twice daily or 180mg once daily.

Allegra Orally Disintegrating Tablet

- Children 6-11 Years: 30mg twice daily.

Allegra Oral Suspension

- Children 2-11 Years with Seasonal Allergic Rhinitis: 30mg (5mL) twice daily.
- Children 2-11 Years with Chronic Idiopathic Urticaria: 30mg (5mL) twice daily.
- Children 6 Months to <2 Years with Chronic Idiopathic Urticaria: 15mg (2.5mL) twice daily.

Clarinet

- Children 6-11 Months: 2mL (1mg) of the syrup once daily.
- Children 12 Months to 5 Years: ½ teaspoonful (1.25mg) of the syrup once daily.
- Children 6 -11 years: 1 teaspoonful (2.5 mg) of the syrup once daily or one 2.5mg RediTab once daily.
- Adults and Children 12 Years and Older: 5mg once daily.

Claritin

- Children 2-5 Years: 5mg once daily.
- Adults and Children 6 Years of Age and Older: 10mg once daily.

Xyzal

- Children 6-11 Years: 2.5mg (½ tablet) once daily in the evening.
- Adults and Children 12 Years and Older: 5mg once daily in the evening. Some patients may be adequately controlled by 2.5mg (½ tablet) once daily in the evening.

Xyzal Oral Solution

- Children 6-11 Years: 5mL (2.5mg) once daily in the evening.
- Adults and Children 12 Years and Older: 10mL (5mg) once daily in the evening. Some patients may be adequately controlled by 2.5mg (½ tablet) once daily in the evening.

Zyrtec

- Children 6 Months to <2 Years: 2.5mg (½ teaspoonful) of the syrup once daily. The dose in children 12-23 months of age can be increased to a max of 5mg per day, given as ½ teaspoonful every 12 hours. Syrup is recommended for children under the age of 2 years.
- Children 2-5 Years: 2.5mg (½ teaspoonful) of the syrup once daily. The dosage in this age group can be increased to a maximum dose of 5mg per day given as 1 teaspoon syrup once a day or one ½ teaspoon syrup given every 12 hours, or one 5 mg chewable tablet once daily.
- Children 6-11 Years: 5mg or 10mg once daily depending on symptom severity. The time of administration may be varied to suit individual patient needs.
- Adults and Children 12 Years and Older: 5mg or 10mg per day in adults and children 12 years and older, depending on symptom severity. Most patients in clinical trials started at 10mg. Zyrtec is given as a single daily dose. The time of administration may be varied to suit individual patient needs.

REFERENCES

1. Allegra. Prescribing Information. Sanofi-Aventis. July 2007.
2. Clarinet. Prescribing Information. Schering Corporation. February 2007.
3. Claritin. Prescribing Information. Available from: <http://www.claritin.com/claritin/hcp/index.jsps>. Accessed July 2009.
4. Xyzal. Prescribing Information. UCB, Inc. January 2008.
5. Zyrtec. Prescribing Information. Available from: <http://www.zyrtecprofessional.com/index.html>. Accessed July 2009.
6. Facts and Comparisons, St. Louis, 2009 eFacts CliniSphere Version ISBN 1-57439-036-8.

Revision/Review Date: 8/2009

Associated Policy: Prior Authorization of Medications 236.200

NOTE: Pharmacist reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.

SELECT HEALTH PRIOR AUTHORIZATION CRITERIA

SEDATIVE HYPNOTICS

STATUS Preferred, Pays at Point-of-Sale (First Line)

AMBIEN (zolpidem) Tablet: 5mg, 10mg

SONATA (zaleplon) Capsule: 5mg, 10mg

STATUS Non-Preferred, Requires Prior Authorization (Second Line)

AMBIEN CR (zolpidem extended-release) Tablet: 6.25mg, 12.5mg

LUNESTA (eszopiclone) Tablet: 1mg, 2mg, 3mg

ROZEREM (ramelteon) Tablet: 8mg

PA CRITERIA FOR APPROVAL

- Diagnosis of insomnia.
- Documented trial and failure or intolerance to Ambien (Zolpidem) AND Sonata (Zaleplon) for at least 2 weeks (14 days) of therapy each.

NOTE: Rozerem can be approved as a first line agent if there is a history of substance abuse.

If the above conditions are met, the request will be approved with a 12 month duration; if the above conditions are not met, the request will be referred to a Pharmacist for medical necessity review.

FDA INDICATIONS

- **Ambien:** Short-term treatment of insomnia characterized by difficulties with sleep initiation.
- **Ambien CR:** Treatment of insomnia characterized by difficulties with sleep onset and/or sleep maintenance (as measured by wake time after sleep onset).
- **Lunesta:** Treatment of insomnia.
- **Rozerem:** Treatment of insomnia characterized by difficulty with sleep onset.
- **Sonata:** Short-term treatment of insomnia.

DOSAGE AND ADMINISTRATION

- **Ambien:** The recommended dose for adults is 10mg immediately before bedtime. For certain individuals, 5mg may be a sufficient dose.
- **Ambien CR:** The recommended dose for adults is 12.5mg immediately before bedtime. For certain individuals, 6.25mg may be a sufficient dose.
- **Lunesta:** The recommended starting dose for Lunesta for most non-elderly adults is 2 mg immediately before bedtime. Dosing can be initiated at or raised to 3mg if clinically indicated, since 3mg is more effective for sleep maintenance. The recommended starting dose of Lunesta for elderly patients whose primary complaint is difficulty falling asleep is 1mg immediately before bedtime. In these patients, the dose may be increased to 2mg if clinically indicated. For elderly patients whose primary complaint is difficulty staying asleep, the recommended dose is 2mg immediately before bedtime.
- **Rozerem:** The recommended dose is 8mg taken within 30 minutes of going to bed.
- **Sonata:** The recommended dose for adults is 10mg immediately before bedtime or after the patient has gone to bed and has experienced difficulty falling asleep. For certain individuals, 5mg may be a sufficient dose.

REFERENCES

1. Ambien. Prescribing Information. Sanofi-Aventis. May 2008.
2. Ambien CR. Prescribing Information. Sanofi-Aventis. January 2008.
3. Lunesta. Prescribing Information. Sepracor, Inc. February 2008.
4. Rozerem. Prescribing Information. Takeda Pharmaceuticals America, Inc. October 2008.
5. Facts and Comparisons, St. Louis, 2009 eFacts CliniSphere Version ISBN 1-57439-036-8.

Revision/Review Date: 8/2009

Associated Policy: Prior Authorization of Medications 236.200

NOTE: Pharmacist reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.

SELECT HEALTH PRIOR AUTHORIZATION CRITERIA

SINGULAIR (montelukast) Tablet: 10mg; Chewable Tablet: 4mg, 5mg; Granule: 4mg

STATUS Preferred

PA CRITERIA FOR APPROVAL

- Singulair 4mg and 5mg are preferred and pay at point-of-sale.
- Singulair 10mg is preferred for patients <19 years of age and pays at point-of-sale.
- Singulair 10mg is a first line agent for diagnosis of asthma in patients 19 years of age and older, and a second-line agent for diagnosis of allergic rhinitis in patients 19 years of age and older with use of asthma medication(s) in the previous 12 months or concurrent prescription for any of the following: leukotriene modifier (LTM), short acting B₂ agonist (SABA), long acting B₂ agonist (LABA), inhaled corticosteroids (ICS), cromolyn sodium, xanthine, non-sedating antihistamine (NSA), intranasal steroids, intranasal antihistamines, or any combination of the above.

If the above conditions are met, the request will be approved with a 12 month duration; if the above conditions are not met, the request will be referred to a Pharmacist for medical necessity review.

FDA INDICATIONS

Asthma:

Montelukast is indicated for the prophylaxis and chronic treatment of asthma in adults and children 12 months of age and older.

Allergic Rhinitis:

Montelukast is indicated for the relief of symptoms of allergic rhinitis (seasonal allergic rhinitis in adults and children 2 years of age and older), and perennial allergic rhinitis in adults and children 6 months of age and older.

Exercise-Induced Bronchoconstriction:

Montelukast is indicated for prevention of exercise-induced bronchoconstriction in patients 15 years of age and older.

DOSAGE AND ADMINISTRATION

Singulair is taken once daily.

For asthma, dose should be taken in the evening.

For seasonal allergic rhinitis, the time of administration should be individualized to suit patient needs.

For exercise-induced bronchoconstriction, dose should be taken at least 2 hours before exercise and should not be taken within 24 hours of a previous dose.

Adults 15 years and older: Recommended dose: one 10 mg tablet daily

Pediatric patients 6-14 years of age: Recommended dose: one 5 mg chewable tablet daily

Pediatric patients 2-5 years of age: Recommended dose: one 4 mg chewable tablet daily

Pediatric patients 6 to 23 months of age: Recommended dose: one packet of 4 mg oral granules daily

REFERENCES

1. Singulair. Prescribing Information. Merck, Inc. November 2009.
2. Facts and Comparisons, St. Louis, 2010 eFacts CliniSphere Version ISBN 1-57439-036-8.
3. Guidelines for the diagnosis and management of asthma. National Heart, Lung and Blood Institute. Full Report. 28 August 2007. Available at: <http://www.nhlbi.nih.gov/guidelines/asthma/asthgdln.pdf>.

Revision/Review Date: 2/2010

Associated Policy: Prior Authorization of Medications 236.200

NOTE: Pharmacist reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.

SELECT HEALTH PRIOR AUTHORIZATION CRITERIA

SPORANOX (itraconazole) Capsule: 100mg; Oral Solution: 10mg/mL

STATUS Preferred

PA CRITERIA FOR APPROVAL

- Immunocompromised patient.

OR

- Trial and failure or intolerance to a preferred oral antifungal.

OR

- Following completion of or intolerance to amphotericin B therapy.

OR

- Diagnosis of aspergillosis.

If any of the above conditions are met, the request will be approved with a 3 month duration; if the above conditions are not met, the request will be referred to a Pharmacist for medical necessity review.

FDA INDICATIONS

Sporanox Capsules:

Indicated for the treatment of the following fungal infections in immunocompromised and non-immunocompromised patients:

- Blastomycosis, pulmonary and extrapulmonary.
- Histoplasmosis, including chronic cavitory pulmonary disease and disseminated, non-meningeal histoplasmosis.
- Aspergillosis, pulmonary and extrapulmonary, in patients who are intolerant of or who are refractory to amphotericin B therapy.

Indicated for the treatment of the following fungal infections in non-immunocompromised patients:

- Onychomycosis of the toenail, with or without fingernail involvement, due to dermatophytes (tinea unguium).
- Onychomycosis of the fingernail due to dermatophytes (tinea unguium).

Sporanox Oral Solution:

- Empiric therapy of febrile neutropenic patients with suspected fungal infections. In a comparative trial, the overall response rate for itraconazole-treated subjects was higher than for amphotericin B-treated subjects. However, compared to amphotericin B-treated subjects, a larger number of itraconazole-treated subjects discontinued treatment due to persistent fever and a change in antifungal medication due to fever. Whereas, a larger number of amphotericin B-treated subjects discontinued due to drug intolerance.
- Treatment of oropharyngeal and esophageal candidiasis.

DOSAGE AND ADMINISTRATION

Sporanox Capsules:

- *Blastomycosis and Histoplasmosis:* 200mg (2 capsules) once daily. If there is no obvious improvement, or there is evidence of progressive fungal disease, the dose should be increased in 100mg increments to a maximum of 400mg daily. Doses above 200mg/day should be given in two divided doses.
- *Aspergillosis:* 200-400mg daily.
- *Onychomycosis of the Toenails with or without Fingernail Involvement:* 200mg (2 capsules) once daily for 12 consecutive weeks.
- *Onychomycosis of the Fingernails only:* Two treatment pulses, each consisting of 200mg (2 capsules) twice daily (400mg/day) for 1 week. The pulses are separated by a 3 week period without Sporanox.

***Sporanox Capsules should be taken with a full meal to ensure maximal absorption.

***Sporanox Capsules is a different preparation than Sporanox Oral Solution and should not be used interchangeably.

Sporanox Oral Solution:

- *Treatment of Oropharyngeal and Esophageal Candidiasis:* The solution should be vigorously swished in the mouth (10mL at a time) for several seconds and swallowed. The recommended dosage of Sporanox Oral Solution for oropharyngeal candidiasis is 200mg (20mL) daily for 1 to 2 weeks. Clinical signs and symptoms of oropharyngeal candidiasis generally resolve within several days. For patients with oropharyngeal candidiasis unresponsive/refractory to treatment with fluconazole tablets, the recommended dose is 100mg (10mL) twice daily. For patients responding to therapy, clinical response will be seen in 2 to 4 weeks. Patients may be expected to relapse shortly after discontinuing therapy. Limited data on the safety of long-term use (>6 months) of Sporanox Oral Solution are available at this time. The recommended dosage of Sporanox Oral Solution for esophageal candidiasis is 100mg (10mL) daily for a minimum treatment of three weeks. Treatment should continue for 2 weeks following resolution of symptoms. Doses up to 200mg (20mL) per day may be used based on medical judgement of the patient's response to therapy. Only Sporanox Oral Solution has been demonstrated effective for oral and/or esophageal candidiasis.

***Sporanox Oral Solution should be taken with a full meal to ensure maximal absorption.

***Sporanox Oral Solution is a different preparation than Sporanox Capsules and should not be used interchangeably.

REFERENCES

1. Sporanox Capsules. Prescribing Information. PriCara. March 2009.
2. Sporanox Oral Solution. Prescribing Information. Janssen Pharmaceutica. May 2008.
3. Facts and Comparisons, St. Louis, 2010 eFacts CliniSphere Version ISBN 1-57439-036-8.
4. FDA Drug Discontinuations. Sporanox (Itraconazole) Injection. Available from:
<http://www.fda.gov/cder/drug/shortages/Sporanox-10-11-2007.pdf>. Updated 11 October 2007. Accessed 20 December 2007.

Revision/Review Date: 2/2010

Associated Policy: Prior Authorization of Medications 236.200

NOTE: Pharmacist reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.

SELECT HEALTH PRIOR AUTHORIZATION CRITERIA

STIMATE (desmopressin) Nasal Spray: 1.5mg/mL (150mcg/spray)

STATUS Preferred

PA CRITERIA FOR APPROVAL

- Diagnosis of Hemophilia A with Factor VIII coagulant activity levels greater than 5%.
- OR**
- Diagnosis of mild to moderate classic von Willebrand's disease (Type 1) with Factor VIII coagulant activity levels greater than 5%.

If one the above conditions are met, the request will be approved for a 12 month duration; if the above conditions are not met, the request will be referred to a Pharmacist for medical necessity review.

FDA INDICATIONS

- Stimate is indicated for patients with Hemophilia A with Factor VIII coagulant activity levels greater than 5%.
- Stimate will stop bleeding in patients with Hemophilia A with episodes of spontaneous or trauma-induced injuries such as hemarthroses, intramuscular hematomas or mucosal bleeding.
- Stimate is indicated for patients with mild to moderate von Willebrand's disease (Type I) with Factor VIII coagulant activity levels greater than 5%.
- Stimate will stop bleeding in mild to moderate von Willebrand's disease patients with episodes of spontaneous or trauma-induced injuries such as hemarthroses, intramuscular hematomas, mucosal bleeding or menorrhagia.

DOSAGE AND ADMINISTRATION

- Stimate is administered by nasal insufflation, one spray per nostril, to produce a total dose of 300mcg.
- In patients weighing less than 50kg, 150mcg is administered as a single spray.
- If Stimate is used preoperatively, it should be administered 2 hours prior to the scheduled procedure.

REFERENCES

1. Stimate. Prescribing Information. CSL Behring. September 2007.
2. Facts and Comparisons, St. Louis, 2010 eFacts CliniSphere Version ISBN 1-57439-036-8.

Revision/Review Date: 2/2010

Associated Policy: Prior Authorization of Medications 236.200

NOTE: Pharmacist reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.

SELECT HEALTH PRIOR AUTHORIZATION CRITERIA

STRATTERA (atomoxetine) Capsule: 10mg, 18mg, 25mg, 40mg, 60mg, 80mg, 100mg

STATUS Non-Preferred

PA CRITERIA FOR APPROVAL

- Diagnosis of Attention-Deficit/Hyperactivity Disorder (ADHD).

And patient meets one of the following criteria:

- Documented trial and failure with therapeutic doses or intolerance to at least one drug from each of the following two groups for a minimum of 30 days:
 - Adderall XR (Amphetamine Salts), Dexedrine Spansule (Dextroamphetamine), Vyvanse (Lisdexamfetamine)
 - Concerta (Methylphenidate), Focalin XR (Dexmethylphenidate), Ritalin LA (Methylphenidate)
- History of substance abuse in patient or household.
- Diagnosis of tics or Tourette's syndrome.
- Diagnosis of anxiety disorder.

If the above conditions are met, the request will be approved with a 12 month duration; if the above conditions are not met, the request will be referred to a Pharmacist for medical necessity review.

FDA INDICATION

For the treatment of Attention-Deficit/Hyperactivity Disorder (ADHD).

DOSAGE AND ADMINISTRATION

Initial Treatment:

- Dosing of children and adolescents up to 70kg body weight: Strattera should be initiated at a total daily dose of approximately 0.5mg/kg and increased after a minimum of 3 days to a target total daily dose of approximately 1.2mg/kg administered either as a single daily dose in the morning or as evenly divided doses in the morning and late afternoon/early evening. No additional benefit has been demonstrated for doses higher than 1.2mg/kg/day. The total daily dose in children and adolescents should not exceed 1.4mg/kg or 100mg, whichever is less.
- Dosing of children and adolescents over 70kg body weight and adults: Strattera should be initiated at a total daily dose of 40mg and increased after a minimum of 3 days to a target total daily dose of approximately 80mg administered either as a single daily dose in the morning or as evenly divided doses in the morning and late afternoon/early evening. After 2 to 4 additional weeks, the dose may be increased to a maximum of 100mg in patients who have not achieved an optimal response. There are no data that support increased effectiveness at higher doses. There are no data that support increased effectiveness at higher doses. The maximum recommended total daily dose in children and adolescents over 70kg and adults is 100mg.

Maintenance/Extended Treatment:

It is generally agreed that pharmacological treatment of ADHD may be needed for extended periods. The benefit of maintaining pediatric patients (ages 6-15 years) with ADHD on Strattera after achieving a response in a dose range of 1.2-1.8mg/kg/day was demonstrated in a controlled trial. Patients assigned to Strattera in the maintenance phase were generally continued on the same dose used to achieve a response in the open label phase. The physician who elects to use Strattera for extended periods should periodically reevaluate the long-term usefulness of the drug for the individual patient.

***Strattera may be taken with or without food.

***Strattera can be discontinued without being tapered.

***Strattera capsules are not intended to be opened, they should be taken whole.

***The maximum recommended total daily dose in children and adolescents over 70kg and adults is 100mg.

***The safety of single doses over 120mg and total daily doses above 150mg have not been systematically evaluated.

REFERENCES

1. Strattera. Prescribing Information. Eli Lilly and Company. June 2009.
2. Facts and Comparisons, St. Louis, eFacts 2009 CliniSphere Version ISBN 1-57439-036-8.
3. Pliszka S, AACAP Work Group on Quality Issues. Practice parameter for the assessment and treatment of children and adolescents with attention-deficit/hyperactivity disorder. J Am Acad Child Adolesc Psychiatry. 2007 Jul;46(7):894-921.

Revision/Review Date: 8/2009

Associated Policy: Prior Authorization of Medications 236.200

NOTE: Pharmacist reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.

SELECT HEALTH PRIOR AUTHORIZATION CRITERIA

SUBOXONE (buprenorphine/naloxone) Sublingual Tablet: 2/0.5mg, 8/2mg
SUBUTEX (buprenorphine) Sublingual Tablet: 2mg, 8mg

STATUS Non-Preferred
STATUS Non-Preferred

PA CRITERIA FOR APPROVAL

INITIAL PA

- Patient 16 years of age or older.
- Physician meets all qualifications to prescribe Suboxone/Subutex (Federal, State, and Local).
- Diagnosis of opiate dependence/addiction.
- The risks of using Suboxone/Subutex with alcohol or benzodiazepines have been explained to the patient.
- No untreated or unstable psychiatric conditions that would interfere with Suboxone/Subutex compliance.
- No more than one (1) prior attempt to treat opiate addiction with Suboxone/Subutex within the previous 12 months.
- Documentation of referral to or active involvement in formal counseling by a licensed behavioral health provider (D&A counselor is preferred, but not required). 12-step program participation, by itself, is not acceptable.

If these criteria are met, then an initial maximum of 6 months of Suboxone (1 month dispensed at a time) or up to a total of 4 weeks of Subutex will be authorized, depending upon the request of the physician. If the criteria are not met, a pharmacist review will be necessary to determine whether other factors, such as age, co-morbidities, social situation, or prior treatment considerations, would support medical necessity for the initiation or re-initiation of Suboxone/Subutex.

NOTE: Suboxone and Subutex are not appropriate for use in pain management.

RENEWAL PA

- Consistent use of Suboxone during the prior 6 months, as verified with pharmacy data. If inconsistent use is noted upon database search (this would NOT include changes in Suboxone dosing), then written explanation as to why Suboxone should be continued despite apparent noncompliance would be needed.
- Documentation of 2 urine tests in the past 6 months that are negative for opiates since previous authorization.
- Documentation of consistent participation in formal counseling by a licensed behavioral health provider since previous authorization (D&A counselor is preferred, but not required). 12-step program participation, by itself, is not acceptable.
- For patients consistently off opiates and taking Suboxone for an extended period of time and who successfully completed prescribed formal D&A counseling programs, documentation of active engagement in “after-care” programs, such as NA or AA equivalent, will be accepted instead of the above formal counseling requirement.
- Documentation of ongoing behavioral health care for co-existing behavioral health disorders.
- If concurrent use of a benzodiazepine identified in claim system during the initial PA period, renewals must meet the additional following criteria: Must have DSM-IV diagnosis of generalized anxiety disorder (GAD) or panic disorder that is substantiated by a board certified addictionologist or psychiatrist. Diagnosis must be accompanied by justification for concurrent use of a benzodiazepine from board certified addictionologist or psychiatrist.

If these criteria are met, then an additional 6 months of Suboxone will be authorized (1 month dispensed at a time). If the criteria are not met, physician review will be necessary to determine whether other factors would support medical necessity for continuation of Suboxone.

FDA INDICATION

Suboxone and Subutex are indicated for the treatment of opioid dependence.

DOSAGE AND ADMINISTRATION

Subutex or Suboxone is administered sublingually as a single daily dose in the range of 12 to 16mg/day. When taken sublingually, Suboxone and Subutex have similar clinical effects and are interchangeable. There are no adequate and well-controlled studies using Suboxone as initial medication. Subutex contains no naloxone and is preferred for use during induction. Following induction, Suboxone, due to the presence of naloxone, is preferred when clinical use includes unsupervised administration. The use of Subutex for unsupervised administration should be limited to those patients who cannot tolerate Suboxone, for example those patients who have been shown to be hypersensitive to naloxone.

NOTE: It is assumed that since the prescribing practitioner has the appropriate DEA designation to prescribe this medication, the prescribing practitioner has had the full training in its proper use.

REFERENCES

9. Facts and Comparisons, St. Louis, 2010 eFacts CliniSphere Version ISBN 1-57439-036-8.
10. Suboxone & Subutex. Prescribing Information. Reckitt Benckiser Pharmaceuticals, Inc. September 2006.

Revision/Review Date: 2/2010

Associated Policy: Prior Authorization of Medications 236.200

NOTE: Pharmacist reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.

SELECT HEALTH PRIOR AUTHORIZATION CRITERIA

SYMLIN (pramlintide) Vial: 600mcg/mL
SYMLINPEN (pramlintide) Pen: 1000mcg/mL

STATUS Non-Preferred
STATUS Non-Preferred

PA CRITERIA FOR APPROVAL

Type 1 Diabetes Mellitus:

- Diagnosis of Type 1 Diabetes Mellitus.
- Patient ≥ 15 years of age.
- HbA1C $\leq 9\%$.
- Documented trial and failure of optimal mealtime insulin therapy.

Type 2 Diabetes Mellitus:

- Diagnosis of Type 2 Diabetes Mellitus.
- Patient ≥ 15 years of age.
- HbA1C $\leq 9\%$.
- Documented trial and failure with therapeutic doses or contraindication/intolerance to at least one preferred sulfonylurea.
- Documented trial and failure with therapeutic doses or contraindication/intolerance to metformin.
- Documented trial and failure of optimal mealtime insulin therapy.

If the above conditions are met, the request will be approved with a 12 month duration; if the above conditions are not met, the request will be referred to a Pharmacist for medical necessity review.

FDA INDICATIONS

- **Type 1 Diabetes Mellitus:** As an adjunct treatment in patients who use mealtime insulin therapy and who have failed to achieve desired glucose control despite optimal insulin therapy.
- **Type 2 Diabetes Mellitus:** As an adjunct treatment in patients who use mealtime insulin therapy and who have failed to achieve desired glucose control despite optimal insulin therapy, with or without a concurrent sulfonylurea agent and/or metformin.

DOSAGE AND ADMINISTRATION

Symlin dosage differs depending on whether the patient has type 1 or type 2 diabetes (see below). When initiating therapy with Symlin, initial insulin dose reduction is required in all patients (both type 1 and type 2) to reduce the risk of insulin-induced hypoglycemia. As this reduction in insulin can lead to glucose elevations, patients should be monitored at regular intervals to assess Symlin tolerability and the effect on blood glucose, so that individualized insulin adjustments can be initiated. If Symlin therapy is discontinued for any reason (e.g., surgery or illnesses), the same initiation protocol should be followed when Symlin therapy is re-instituted (see below).

Initiation of Symlin Therapy in Patients With Type 1 Diabetes:

In patients with type 1 diabetes, Symlin should be initiated at a dose of 15mcg and titrated at 15-mcg increments to a maintenance dose of 30mcg or 60mcg as tolerated. Patients should be instructed to:

- Initiate Symlin at a starting dose of 15mcg subcutaneously, immediately prior to major meals.
- Reduce preprandial, rapid-acting or short-acting insulin dosages, including fixed-mix insulins (e.g., 70/30) by 50%.
- Monitor blood glucose frequently, including pre- and post-meals and at bedtime.
- Increase the Symlin dose to the next increment (30mcg, 45mcg, or 60mcg) when no clinically significant nausea has occurred for at least 3 days. Symlin dose adjustments should be made only as directed by the healthcare professional. If significant nausea persists at the 45 or 60mcg dose level, the Symlin dose should be decreased to 30mcg. If the 30mcg dose is not tolerated, discontinuation of Symlin therapy should be considered.
- Adjust insulin doses to optimize glycemic control once the target dose of Symlin is achieved and nausea (if experienced) has subsided. Insulin dose adjustments should be made only as directed by the healthcare professional.
- Contact a healthcare professional skilled in the use of insulin to review Symlin and insulin dose adjustments at least once a week until a target dose of Symlin is achieved, Symlin is well-tolerated, and blood glucose concentrations are stable.

Initiation of Symlin Therapy in Patients With Insulin-Using Type 2 Diabetes:

In patients with insulin-using type 2 diabetes, Symlin should be initiated at a dose of 60mcg and increased to a dose of 120mcg as tolerated. Patients should be instructed to:

- Initiate Symlin at 60mcg subcutaneously, immediately prior to major meals.
- Reduce preprandial, rapid-acting or short-acting insulin dosages, including fixed-mix insulins (70/30) by 50%.
- Monitor blood glucose frequently, including pre- and post-meals and at bedtime.
- Increase the Symlin dose to 120mcg when no clinically significant nausea has occurred for 3-7 days. Symlin dose adjustments should be made only as directed by the healthcare professional. If significant nausea persists at the 120mcg dose, the Symlin dose should be decreased to 60mcg.
- Adjust insulin doses to optimize glycemic control once the target dose of Symlin is achieved and nausea (if experienced) has subsided. Insulin dose adjustments should be made only as directed by the healthcare professional.
- Contact a healthcare professional skilled in the use of insulin to review Symlin and insulin dose adjustments at least once a week until a target dose of Symlin is achieved, Symlin is well-tolerated, and blood glucose concentrations are stable.

Once Target Dose of Symlin is Achieved in Type 1 or Type 2 Patients:

After a maintenance dose of Symlin is achieved, both insulin-using patients with type 1 diabetes and patients with type 2 diabetes should be instructed to:

- Adjust insulin doses to optimize glycemic control once the target dose of Symlin is achieved and nausea (if experienced) has subsided. Insulin dose adjustments should be made only as directed by a healthcare professional.
- Contact a healthcare professional in the event of recurrent nausea or hypoglycemia. An increased frequency of mild to moderate hypoglycemia should be viewed as a warning sign of increased risk for severe hypoglycemia.

Administration:

Symlin should be administered subcutaneously immediately prior to each major meal (≥ 250 kcal or containing ≥ 30 g of carbohydrate). Symlin should be at room temperature before injecting to reduce potential injection site reactions. Each Symlin dose should be administered subcutaneously into the abdomen or thigh (administration into the arm is not recommended because of variable absorption). Injection sites should be rotated so that the same site is not used repeatedly. The injection site selected should also be distinct from the site chosen for any concomitant insulin injection. Symlin and insulin should always be administered as separate injections. Symlin should not be mixed with any type of insulin. If a Symlin dose is missed, wait until the next scheduled dose and administer the usual amount.

Conversion of Symlin Dose to Insulin Unit Equivalents

Dosage Prescribed (mcg)	Increment Using a U-100 Syringe (Units)	Volume (cc or mL)
15	2.5	0.025
30	5	0.05
45	7.5	0.075
60	10	0.1
120	20	0.2

REFERENCES

1. Symlin. Prescribing Information. Amylin Pharmaceuticals, Inc. July 2008.
2. Whitehouse F, Kruger DF, et al. A randomized study and open-label extension evaluating the long-term efficacy of pramlintide as an adjunct to insulin therapy in type 1 diabetes. *Diabetes Care*. April 2002; 25(4):724-30.
3. Thompson RG, Pearson L, et al. Pramlintide, a synthetic analog of human amylin, improves the metabolic profile of patients with type 2 diabetes using insulin. *Diabetes Care*. June 1998;21(6):987-93.
4. Hollander PA, Levy P, et al. Pramlintide as an adjunct to insulin therapy improves long-term glycemic and weight control in patients with type 2 diabetes. *Diabetes Care*. March 2003;26(3):784-90.
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Revision/Review Date: 8/2009

Associated Policy: Prior Authorization of Medications 236.200

NOTE: Pharmacist reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.

SELECT HEALTH PRIOR AUTHORIZATION CRITERIA

TOBACCO CESSATION PRODUCTS

STATUS Preferred, Pays at Point-of-Sale

CHANTIX (varenicline) Tablet: 0.5mg, 1mg

ZYBAN (bupropion sustained-release) Tablet: 150mg

STATUS Preferred, Requires Prior Authorization

NICOTINE PATCH (generic) Patch: 7mg/day, 11mg/day, 14mg/day, 21mg/day, 22mg/day

NICOTINE GUM (generic) Gum: 2mg, 4mg

NOTE: Prior authorization requires can come from a pharmacist or physician.

STATUS Non-Preferred, Requires Prior Authorization

NICOTINE LOZENGE (generic) Lozenge: 2mg, 4mg

NICOTROL INHALER (nicotine) Cartridge: 10mg

NICOTROL NS (nicotine) Nasal Spray: 10mg/mL

NOTE: Prior authorization request can only come from a physician.

PA CRITERIA FOR APPROVAL

Bupropion SR:

- Zyban will process at point-of-sale.

Chantix & Nicotine Replacement:

- Chantix will process at point-of-sale. Patients are limited to 3 months (12 weeks) of therapy on a rolling 12 month calendar year.
- Members are limited to 1 nicotine replacement product at a time (not including Zyban). Multiple nicotine replacement products can be tried over a course of 3 months, but each product will count toward the 3 month (90 day) maximum (ex. member uses the patch for 2 months and then wants to switch to the Chantix they would only be approved for 1 month...for a total of 3 months of treatment).
- For approval of non-preferred products (lozenge, inhaler, and nasal spray), member must have a medical reason for not using the patch or gum (ex. allergic reaction to patch).
- Approval length for nicotine replacement products will be for 3 consecutive months (90 days) per rolling 12-month period. For example, a member cannot use the patch for 1 month, be off for 4 months, and then start back on it again...the 3 month coverage is consecutive.

MONTHLY QUANTITY LIMITS

- Chantix: 56 tablets
- Zyban: 60 tablets
- Nicotine Patch: 30 patches
- Nicotine Gum: 330 count
- Nicotine Lozenge: 216 lozenges
- Nicotine Inhaler: 2 systems (336 count)
- Nicotrol NS: 2 systems (eight 10mL bottles)

REFERENCE

1. Facts and Comparisons, St. Louis, 2010 eFacts CliniSphere Version ISBN 1-57439-036-8.

Revision/Review Date: 2/2010

Associated Policy: Prior Authorization of Medications 236.200

NOTE: Pharmacist reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.

SELECT HEALTH PRIOR AUTHORIZATION CRITERIA

TOPROL XL (metoprolol succinate) Tablet: 25mg, 50mg, 100mg, 200mg

STATUS Non-Preferred

PA CRITERIA FOR APPROVAL

Heart Failure:

- Diagnosis of heart failure.

If the above conditions are met, the request will be approved with a 12 month duration; if the above conditions are not met, the request will be referred to a Pharmacist for medical necessity review.

Hypertension:

- Diagnosis of hypertension.
- Documented trial and failure or intolerance with therapeutic doses with at least three of the following medications: atenolol, bisoprolol, carvedilol, labetalol, metoprolol tartrate, pindolol, nadolol, propranolol and timolol.

If the above conditions are met, the request will be approved with a 12 month duration; if the above conditions are not met, the request will be referred to a Pharmacist for medical necessity review.

Angina Pectoris:

- Diagnosis of angina pectoris.
- Documented trial and failure or intolerance with therapeutic doses of with at least two of the following medications: atenolol, bisoprolol, carvedilol, metoprolol tartrate, nadolol, propranolol.

If the above conditions are met, the request will be approved with a 12 month duration; if the above conditions are not met, the request will be referred to a Pharmacist for medical necessity review.

Concurrent Use With Anticonvulsant(s):

- Patient is currently taking anticonvulsant(s).

NOTE: Toprol XL will process at point-of-sale if there is a history of an anticonvulsant in the patient's history.

If the above conditions are met, the request will be approved with a 12 month duration; if the above conditions are not met, the request will be referred to a Pharmacist for medical necessity review.

FDA INDICATIONS

- Toprol XL is indicated for the treatment of hypertension. It may be used alone or in combination with other antihypertensive agents.
- Toprol XL is indicated in the long-term treatment of angina pectoris, to reduce angina attacks and to improve exercise intolerance.
- Toprol XL is indicated for the treatment of stable, symptomatic (NYHA Class II or III) heart failure of ischemic, hypertensive, or cardiomyopathic origin. It was studied in patients already receiving ACE inhibitors, diuretics, and, in the majority of cases, digitalis. In this population, Toprol XL decreased the rate of mortality plus hospitalization, largely through a reduction in cardiovascular mortality and hospitalizations for heart failure.

DOSAGE AND ADMINISTRATION

Toprol XL is an extended release tablet intended for once daily administration. For treatment of hypertension and angina, when switching from immediate release metoprolol to Toprol XL, the same daily dose of Toprol XL should be used. Dosages of Toprol XL should be individualized and titration may be needed in some patients. Toprol XL tablets are scored and can be divided; however, the whole or half tablets should be swallowed whole and not chewed or crushed.

Hypertension:

The usual initial dosage is 25-100mg daily in a single dose, whether used alone or added to a diuretic. The dosage may be increased at weekly (or longer) intervals until optimum blood pressure reduction is achieved. In general, the maximum effect of any given dosage level will be apparent after 1 week of therapy. Dosages above 400mg per day have not been studied.

Pediatric Hypertensive Patients 6 Years of Age and Older:

A pediatric clinical hypertension study in patients 6-16 years of age did not meet its primary endpoint (dose response for reduction in SBP), however some other endpoints demonstrated effectiveness. If selected for treatment, the recommended starting dose of Toprol XL is 1.0mg/kg once daily however, the maximum initial dose should not exceed 50mg once daily. The minimum available dose is one half of the 25mg Toprol XL tablet. Dosage should be adjusted according to blood pressure response. Doses above 2.0mg/kg (or in excess of 200mg) once daily have not been studied in pediatric patients. Toprol XL is not recommended in pediatric patients <6 years of age.

Angina Pectoris:

The dosage of Toprol XL should be individualized. The usual initial dosage is 100mg daily, given in a single dose. The dosage may be gradually increased at weekly intervals until optimum clinical response has been obtained or there is a pronounced showing of the heart rate. Dosages above 400mg per day have not been studied. If treatment is to be discontinued, the dosage should be reduced gradually over a period of 1-2 weeks.

Heart Failure:

Dosage must be individualized and closely monitored during up-titration. Prior to initiation of Toprol XL, the dosing of diuretics, ACE inhibitors, and digitalis (if used) should be stabilized. The recommended starting dose of Toprol XL is 25mg once daily for two weeks in patients with NYHA Class II heart failure and 12.5mg once daily in patients with more severe heart failure. The dose should then be doubled every two weeks to the highest dosage level tolerated by the patient or up to 200mg of Toprol XL. If transient worsening of heart failure occurs, it may be treated with increased doses of diuretics, and it may also be necessary to lower the dose of Toprol XL or temporarily discontinue it. The dose of Toprol XL should not be increased until symptoms of worsening heart failure have been stabilized. Initial difficulty with titration should not preclude later attempts to introduce Toprol XL. If heart failure patients experience symptomatic bradycardia, the dose of Toprol XL should be reduced.

REFERENCES

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Revision/Review Date: 5/2010

Associated Policy: Prior Authorization of Medications 236.200

NOTE: Pharmacist reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.

SELECT HEALTH PRIOR AUTHORIZATION CRITERIA

SEROTONIN RECEPTOR AGONISTS (TRIPTANS)

STATUS Preferred, Pays at Point-of-Sale

IMITREX (sumatriptan) Tablet: 25mg, 50mg, 100mg; Nasal Spray: 5mg, 20mg; Subcutaneous Injection: 4mg/0.5mL, 6mg/0.5mL

STATUS Non-Preferred, Requires Prior Authorization

AMERGE (naratriptan) Tablet: 1mg, 2.5mg

AXERT (almotriptan) Tablet: 6.25mg, 12.5mg

FROVA (frovatriptan) Tablet: 2.5mg

MAXALT (rizatriptan) Tablet: 5mg, 10mg

MAXALT-MLT (rizatriptan) Orally Disintegrating Tablet: 5mg, 10mg

RELPAX (eletriptan) Tablet: 20mg, 40mg

TREXIMET (sumatriptan/naproxen) Tablet: 85mg/500mg

ZOMIG (zolmitriptan) Tablet: 2.5mg, 5mg; Nasal Spray: 5mg

ZOMIG-ZMT (zolmitriptan) Orally Disintegrating Tablet: 2.5mg, 5mg

PA CRITERIA FOR APPROVAL

Imitrex:

- Diagnosis of migraine headaches.
- Diagnosis of cluster headaches (Imitrex injection only).
- An automatic approval at the point-of-sale will occur if the quantities prescribed do not exceed 12 tablets per 30 days, 6 nasal spray units per 30 days, and 4 injections per 30 days.

Non-Preferred Agents (Excluding Treximet):

- Diagnosis of migraine headaches.
- Documented trial and failure or intolerance to Imitrex.

If the above conditions are met, the request will be approved with a 12 month duration with a quantity not to exceed 12 tablets per 30 days and 6 nasal spray units per 30 days; if the above conditions are not met, the request will be referred to a Pharmacist for medical necessity review.

Treximet:

- Requests for Treximet should be directed to using the two individual agents (sumatriptan and naproxen).

Quantities Greater than Allowed per 30 days if Prior Authorization Criteria Met:

If the patient requires doses greater than the set limits above after meeting approval, the request will be referred to a Pharmacist for medical necessity review.

FDA INDICATIONS

Serotonin receptor agonists are indicated for the acute treatment of migraine attacks with or without aura in adults. They are not indicated for prophylactic therapy of migraine or for use in the management of hemiplegic or basilar migraine. Imitrex injection is also indicated for treatment of cluster headache episodes in adults.

DOSAGE AND ADMINISTRATION

Amerge:

- Tablet: 1 or 2.5mg at onset; may repeat after 4 hours. Do not to exceed 5mg in a 24 hour period.

Axert:

- Tablet 6.25 or 12.5mg at onset; may repeat after 2 hours. Do not exceed 2 doses in a 24 hour period.

Frova:

- Tablet 2.5mg at onset; may repeat after 2 hours. Do not exceed 7.5mg in a 24 hour period.

Imitrex:

- Tablet: 25, 50 or 100mg at onset; may repeat after 2 hours. Do not exceed 200mg in a 24 hour period.
- Nasal Spray: 5, 10 (5 mg dose in each nostril) or 20mg (1 spray) at onset; may repeat after 2 hours. Do not exceed 40mg in a 24 hour period.
- Subcutaneous Injection: 4 or 6mg subcutaneously at onset; may repeat in 1 hour. Do not exceed 6mg/dose and 12mg in a 24 hour period.

Maxalt:

- Tablet: 5 or 10mg at onset; may repeat after 2 hours. Do not exceed 30mg in a 24 hour period.
- Orally Disintegrating Tablet: 5 or 10mg at onset; may repeat after 2 hours. Do not exceed 30mg in a 24 hour period.

Relpax:

- Tablet: 20 or 40mg at onset; may repeat after 2 hours. Do not exceed a 40mg/dose or 80mg in a 24 hour period.

Treximet:

- Tablet: 85mg/500mg at onset; may repeat after 2 hours. Do not exceed 170mg/1000mg in a 24 hour period.

Zomig:

- Tablet: 2.5 or 5mg at onset; may repeat after 2 hours. Do not exceed 10mg in a 24 hour period.
- Orally Disintegrating Tablet: 2.5 or 5mg at onset; may repeat after 2 hours. Do not exceed 10mg in a 24 hour period.
- Nasal Spray: 5mg (1 spray) at onset; may repeat after 2 hours. Do not exceed 10mg in a 24 hour period.

REFERENCES

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12. Micromedex Online Available from: <http://www.thomsonhc.com.db.usip.edu/hcs/librarian>. Accessed April 2008.

Revision/Review Date: 11/2009

Associated Policy: Prior Authorization of Medications 236.200

NOTE: Pharmacist reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.

SELECT HEALTH PRIOR AUTHORIZATION CRITERIA

VICOPROFEN (hydrocodone/ibuprofen) Tablet: 7.5mg/200mg

STATUS Non-Preferred

PA CRITERIA FOR APPROVAL

- Diagnosis of acute pain.

AND

- Documented trial and failure or intolerance to at least three of the following medications: oxycodone/acetaminophen, hydrocodone/acetaminophen, codeine/acetaminophen, or propoxyphene/acetaminophen.

OR

- Documented liver impairment that would warrant avoidance of acetaminophen products.

If the above conditions are met, the request will be approved with a 1 month duration; if the above conditions are not met, the request will be referred to a Pharmacist for medical necessity review.

FDA INDICATIONS

- Vicoprofen is indicated for the short-term (generally less than 10 days) management of acute pain.
- Vicoprofen is not indicated for treatment of such conditions as osteoarthritis or rheumatoid arthritis.

DOSAGE AND ADMINISTRATION

For the short-term (generally less than 10 days) management of acute pain, the recommended dose of Vicoprofen is one tablet every 4-6 hours, as necessary. Dosage should not exceed 5 tablets in a 24-hour period.

REFERENCES

1. Vicoprofen. Prescribing Information. Abbott Laboratories. October 2009.
2. Facts and Comparisons, St. Louis, 2010 eFacts CliniSphere Version ISBN 1-57439-036-8.

Revision/Review Date: 2/2010

Associated Policy: Prior Authorization of Medications 236.200

NOTE: Pharmacist reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.

SELECT HEALTH PRIOR AUTHORIZATION CRITERIA

WEIGHT LOSS MEDICATIONS

STATUS Non-Preferred

ADIPEX-P (phentermine) Capsule: 37.5mg; Tablet: 37.5mg
ALLI (orlistat) Capsule: 60mg
BONTRIL PDM (phendimetrazine) Tablet: 35mg
BONTRIL SLOW-RELEASE (phendimetrazine) Capsule: 105mg
DESOXYN (methamphetamine) Tablet: 5mg
DIDREX (benzphetamine) Tablet: 50mg
IONAMIN (phentermine) Capsule: 15mg, 30mg
MERIDIA (sibutramine) Capsule: 5mg, 10mg, 15mg
PHENTROL (phentermine) Capsule: 15mg, 30mg; Tablet: 8mg
TENUATE (diethylpropion) Tablet: 25mg, 75mg
XENICAL (orlistat) Capsule: 120mg

PA CRITERIA FOR APPROVAL

INITIAL PA:

Obesity in the Absence of Other Risk Factors:

- Patient must be at least 18 years of age.
- Patient must have an initial body mass index (BMI) of 30kg/m² or greater.
- Prescribing physician must submit documentation of patient's starting weight.
- Patient must have received nutritional counseling regarding adherence to dietary guidelines.

Obesity in the Presence of Other Risk Factors:

- Patient must be at least 18 years of age.
- Patient must have an initial body mass index (BMI) of 27kg/m² or greater.
- Patient must have a diagnosis of obesity in the presence of other risk factors (e.g., hypertension, diabetes, dyslipidemia).
- Prescribing physician must submit documentation of patient's starting weight.
- Patient must have received nutritional counseling regarding adherence to dietary guidelines.

If the above conditions are met, the request will be approved with a 1 month duration; if the above conditions are not met, the request will be referred to a Pharmacist for medical necessity review.

NOTE: If a request for Xenical is approved, refer patient to use Alli at the equivalent dosing.

NOTE: Requests for Desoxyn also must first have documented trial and failure at least two other weight loss medications.

RENEWAL PA:

- Prescribing physician must submit documentation of patient's starting weight and current weight.
- Demonstrated weight loss on medication, as shown through documentation of patient's starting weight (from previous month) and current weight.

If the above conditions are met, the request will be approved with a 1 month duration; if the above conditions are not met, the request will be referred to a Pharmacist for medical necessity review.

REFERENCES

1. Lexi-Comp Online. Available from: <http://online.lexi.com>. Accessed 5 April 2010.
2. Facts and Comparisons, St. Louis, eFacts 2010 CliniSphere Version ISBN 1-57439-036-8.
3. Prescription Medication for the Treatment of Obesity. US Department of Health and Human Services. Bethesda, MD. 2007. Available from: www.win.niddk.nih.gov. Accessed 2 March 2009.
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Revision/Review Date: 5/2010

Associated Policy: Prior Authorization of Medications 236.200

NOTE: Pharmacist reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.

SELECT HEALTH PRIOR AUTHORIZATION CRITERIA

XOPENEX (levalbuterol) MDI: 45mcg/puff; Nebulization: 0.31mg/3mL, 0.63mg/3mL, 1.25mg/3mL

STATUS Non-Preferred

PA CRITERIA FOR APPROVAL

- Diagnosis of reversible obstructive airway disease.

AND

- Trial and failure or intolerance to racemic Albuterol due to significant side effects. Patient must try and fail with an equivalent delivery mechanism (i.e.: try and fail racemic Albuterol MDI in order to receive Xopenex MDI). The exception is when side effects are severe enough to warrant a switch from racemic Albuterol to Xopenex, regardless of delivery mechanism.

OR

- Documented history of arrhythmias.

If the above conditions are met, the request will be approved with 12 month duration; if the above conditions are not met, the request will be referred to a Pharmacist for medical necessity review.

FDA INDICATIONS

MDI: For the treatment or prevention of bronchospasm in adults, adolescents, and children 4 years of age and older with reversible obstructive airway disease.

Nebulization: For the treatment or prevention of bronchospasm in adults, adolescents, and children 6 years of age and older with reversible obstructive airway disease.

DOSAGE AND ADMINISTRATION

MDI:

- *Patients 4 years of age and older:* 1-2 inhalations (45-90mcg) every 4 to 6 hours.

Nebulization:

- *Children 6-11 years old:* 0.31mg administered 3 times a day by nebulization, do not exceed 0.63mg three times a day.
- *Adults and Adolescents 12 years of age and older:* 0.63mg administered three times a day, every 6 to 8 hours, by nebulization. Patients who do not respond adequately to this dose may benefit from a dosage of 1.25mg three times a day.

REFERENCES

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2. Xopenex Inhalation Solution. Prescribing Information. Sepracor. August 2007.
3. Facts and Comparisons, St. Louis, 2010 eFacts CliniSphere Version ISBN 1-57439-036-8.
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Revision/Review Date: 2/2010

Associated Policy: Prior Authorization of Medications 236.200

NOTE: Pharmacist reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.

SELECT HEALTH PRIOR AUTHORIZATION CRITERIA

ZOFRAN (ondansetron) Tablet: 4mg, 8mg; Orally Disintegrating Tablet: 4mg, 8mg; Oral Solution: 4mg/5mL
STATUS Preferred

ZOFRAN (ondansetron) Tablet: 24mg
STATUS Non-Preferred

PA CRITERIA FOR APPROVAL

Chemotherapy or Radiation Therapy:

- Current treatment with emetogenic chemotherapy or radiation therapy.

NOTE: An automatic approval at the point-of-sale will occur if the quantities prescribed do not exceed 15 tablets/30 days (4mg & 8mg) or 50mL/30 days (4mg/5mL).

NOTE: Zofran 24mg tablets are non-preferred. Requests for the 24mg tablets should be referred to using the 8mg tablets.

If the above condition is met, the request will be approved with a quantity limit of 15 tablets/30days (4mg & 8mg) or 50mL/30 days for the duration of the chemotherapy or radiation, not to exceed 3 months; if the above condition is not met, the request will be referred to a Pharmacist for medical necessity review. If the request is for a quantity greater than the limits stated above, the request will be referred to a Pharmacist for medical necessity review.

Hyperemesis Gravidarum:

- Diagnosis of hyperemesis gravidarum.
- Dosage does not exceed 4-8mg every 6 hours.

NOTE: An automatic approval at the point-of-sale will occur if the quantities prescribed do not exceed 15 tablets/30 days (4mg & 8mg) or 50mL/30 days (4mg/5mL).

NOTE: Zofran 24mg tablets are non-preferred. Requests for the 24mg tablets should be referred to using the 8mg tablets.

If the above conditions are met, the request will be approved for the remaining duration of the pregnancy or the duration requested (whichever is less); if the above conditions are not met, the request will be referred to a Pharmacist for medical necessity review.

FDA INDICATIONS

- Prevention of nausea and vomiting associated with highly emetogenic cancer chemotherapy, including cisplatin >50 mg/m².
- Prevention of nausea and vomiting associated with initial and repeat courses of moderately emetogenic cancer chemotherapy.
- Prevention of nausea and vomiting associated with radiotherapy in patients receiving either total body irradiation, single high-dose fraction to the abdomen, or daily fractions to the abdomen.
- Prevention of postoperative nausea and/or vomiting. As with other antiemetics, routine prophylaxis is not recommended for patients in whom there is little expectation that nausea and/or vomiting will occur postoperatively. In patients where nausea and/or vomiting must be avoided postoperatively, Zofran Tablets, Zofran Orally Disintegrating Tablets, and Zofran Oral Solution are recommended even where the incidence of postoperative nausea and/or vomiting is low.

DOSAGE AND ADMINISTRATION

Prevention of Nausea and Vomiting Associated With Highly Emetogenic Cancer Chemotherapy:

- The recommended adult oral dosage of Zofran is 24mg given as three 8-mg tablets administered 30 minutes before the start of single-day highly emetogenic chemotherapy, including cisplatin >50 mg/m². Multiday, single-dose administration of a 24mg dosage has not been studied.
- Pediatric Use: There is no experience with the use of a 24mg dosage in pediatric patients.
- Geriatric Use: The dosage recommendation is the same as for the general population.

Prevention of Nausea and Vomiting Associated With Moderately Emetogenic Cancer Chemotherapy:

- The recommended adult oral dosage is one 8mg Zofran Tablet or one 8mg Zofran ODT Tablet or 10mL (2 teaspoonfuls equivalent to 8mg of ondansetron) of Zofran Oral Solution given twice a day. The first dose should be administered 30 minutes before the start of emetogenic chemotherapy, with a subsequent dose 8 hours after the first dose. One 8mg Zofran Tablet or one 8-mg Zofran ODT Tablet or 10mL (2 teaspoonfuls equivalent to 8mg of ondansetron) of Zofran Oral Solution should be administered twice a day (every 12 hours) for 1 to 2 days after completion of chemotherapy.

- Pediatric Use: For pediatric patients 12 years of age and older, the dosage is the same as for adults. For pediatric patients 4 through 11 years of age, the dosage is one 4mg Zofran Tablet or one 4mg Zofran ODT Tablet or 5mL (1 teaspoonful equivalent to 4mg of ondansetron) of Zofran Oral Solution given 3 times a day. The first dose should be administered 30 minutes before the start of emetogenic chemotherapy, with subsequent doses 4 and 8 hours after the first dose. One 4mg Zofran Tablet or one 4mg Zofran ODT Tablet or 5mL (1 teaspoonful equivalent to 4 mg of ondansetron) of Zofran Oral Solution should be administered 3 times a day (every 8 hours) for 1 to 2 days after completion of chemotherapy.
- Geriatric Use: The dosage is the same as for the general population.

Prevention of Nausea and Vomiting Associated With Radiotherapy, Either Total Body Irradiation, or Single High-Dose Fraction or Daily Fractions to the Abdomen:

- The recommended oral dosage is one 8mg Zofran Tablet or one 8mg Zofran ODT Tablet or 10mL (2 teaspoonfuls equivalent to 8mg of ondansetron) of Zofran Oral Solution given 3 times a day.
- For total body irradiation, one 8mg Zofran Tablet or one 8mg Zofran ODT Tablet or 10mL (2 teaspoonfuls equivalent to 8mg of ondansetron) of Zofran Oral Solution should be administered 1 to 2 hours before each fraction of radiotherapy administered each day.
- For single high-dose fraction radiotherapy to the abdomen, one 8mg Zofran Tablet or one 8mg Zofran ODT Tablet or 10mL (2 teaspoonfuls equivalent to 8mg of ondansetron) of Zofran Oral Solution should be administered 1 to 2 hours before radiotherapy, with subsequent doses every 8 hours after the first dose for 1 to 2 days after completion of radiotherapy.
- For daily fractionated radiotherapy to the abdomen, one 8mg Zofran Tablet or one 8mg Zofran ODT Tablet or 10mL (2 teaspoonfuls equivalent to 8 mg of ondansetron) of Zofran Oral Solution should be administered 1 to 2 hours before radiotherapy, with subsequent doses every 8 hours after the first dose for each day radiotherapy is given.
- Pediatric Use: There is no experience with the use of Zofran Tablets, Zofran ODT Tablets, or Zofran Oral Solution in the prevention of radiation-induced nausea and vomiting in pediatric patients.
- Geriatric Use: The dosage recommendation is the same as for the general population.

Postoperative Nausea and Vomiting:

- The recommended dosage is 16mg given as two 8mg Zofran Tablets or two 8mg Zofran ODT Tablets or 20mL (4 teaspoonfuls equivalent to 16 mg of ondansetron) of Zofran Oral Solution 1 hour before induction of anesthesia.
- Pediatric Use: There is no experience with the use of Zofran Tablets, Zofran ODT Tablets, or Zofran Oral Solution in the prevention of postoperative nausea and vomiting in pediatric patients.
- Geriatric Use: The dosage is the same as for the general population.

Dosage Adjustment for Patients with Impaired Renal Function:

- The dosage recommendation is the same as for the general population. There is no experience beyond first-day administration of ondansetron.

Dosage Adjustment for Patients with Impaired Hepatic Function:

- In patients with severe hepatic impairment (Child-Pugh score of 10 or greater), clearance is reduced and apparent volume of distribution is increased with a resultant increase in plasma half-life. In such patients, a total daily dose of 8mg should not be exceeded

REFERENCES

1. Zofran. Prescribing Information. GlaxoSmithKline. February 2006.
2. Facts and Comparisons, St. Louis, 2009 eFacts CliniSphere Version ISBN 1-57439-036-8.
3. Coupland NJ, Bailey JE, Potokar JP, et al. 5-HT₃ receptors, nausea, and serotonin reuptake inhibition. J Clin Psychopharmacol. Apr 1997;17(2):142-3.
4. Leman P. Utility of ondansetron in children with vomiting. Ann Emerg Med (United States). Sept 2002; 40(3):366-7.
5. The National Comprehensive Cancer Network (NCCN) and The American Cancer Society (ACS). Nausea and Vomiting. Treatment Guidelines for Patients with Cancer. Version 1. January 2001.
6. Walker PC, Biglin KE, Constance TD, et al. Promoting the use of oral ondansetron in children receiving cancer chemotherapy. Am J Health Syst Pharm (United States). April 2001;58(7):598-602.
7. The Hyperemesis Education & Research Foundation. Treatment Overview of Hyperemesis Gravidarum. Leesberg (VA);August 2006.

Revision/Review Date: 8/2009

Associated Policy: Prior Authorization of Medications 236.200

NOTE: Pharmacist reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.

SELECT HEALTH PRIOR AUTHORIZATION CRITERIA

ZOVIRAX (acyclovir) Cream: 5%, Ointment: 5%

STATUS Preferred

PA CRITERIA FOR APPROVAL

Zovirax Cream:

- Diagnosis of herpes labialis (cold sores).
- Documented trial and failure or intolerance to Abreva or Denavir.

Zovirax Ointment:

- Diagnosis of venereal herpes.
- Documented trial and failure or intolerance to a preferred oral antiviral.

If the above conditions are met, the request will be approved with a 1 month duration; if the above conditions are not met, the request will be referred to a Pharmacist for medical necessity review.

FDA INDICATIONS

Zovirax Cream:

- Treatment of recurrent herpes labialis (cold sores) in adults and children 12 years of age and older.

Zovirax Ointment:

- Management of initial genital herpes and in limited non-life-threatening mucocutaneous Herpes simplex virus infections in immunocompromised patients.

DOSAGE AND ADMINISTRATION

Zovirax Cream:

- Apply 5 times per day for 4 days.
- Therapy should be initiated as early as possible following onset of signs and symptoms (i.e., during the prodrome or when lesions appear).

Zovirax Ointment:

- Apply sufficient quantity to adequately cover all lesions every 3 hours, 6 times per day for 7 days. The dose size per application will vary depending upon the total lesion area but should approximate a one-half inch ribbon of ointment per 4 square inches of surface area.
- A finger cot or rubber glove should be used when applying Zovirax to prevent autoinoculation of other body sites and transmission of infection to other persons.
- Therapy should be initiated as early as possible following onset of signs and symptoms.

REFERENCES

1. Zovirax Cream. Prescribing Information. GlaxoSmithKline. October 2008.
2. Zovirax Ointment. Prescribing Information. GlaxoSmithKline. October 2008.
3. Facts and Comparisons, St. Louis, 2010 eFacts CliniSphere Version ISBN 1-57439-036-8.

Revision/Review Date: 2/2010

Associated Policy: Prior Authorization of Medications 236.200

NOTE: Pharmacist reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.

SELECT HEALTH PRIOR AUTHORIZATION CRITERIA

ZYVOX (linezolid) Tablet: 600mg; Suspension: 100mg/5mL

STATUS Non-Preferred

PA CRITERIA FOR APPROVAL

- Diagnosis of vancomycin-resistant enterococcus faecium infection, nosocomial pneumonia, complicated skin and skin-structure infection (including diabetic foot infections, without concomitant osteomyelitis), uncomplicated skin and skin structure Infection, methicillin-resistant Staphylococcus aureus, or community-acquired pneumonia.

And patient meets one of the two following criteria:

- Documented history of treatment with Zyvox IV (continuation of therapy, IV to PO conversion).
- Documentation that the infection is susceptible to Zyvox **AND** the patient has failed treatment or is contraindicated to treatment with at least two antibiotics to which the organism is susceptible.

If the above conditions are met, the request will be approved with up to a 1 month duration depending on the type of infection; if the above conditions are not met, the request will be referred to a Pharmacist for medical necessity review.

FDA INDICATIONS

- **Vancomycin-Resistant Enterococcus Faecium Infections:** Including cases with concurrent bacteremia.
- **Nosocomial Pneumonia:** Caused by Staphylococcus aureus (methicillin-susceptible and methicillin-resistant strains), or Streptococcus pneumoniae (including multi-drug resistant strains [MDRSP]).
- **Complicated Skin and Skin Structure Infections, Including Diabetic Foot Infections, without Concomitant Osteomyelitis:** Caused by Staphylococcus aureus (methicillin-susceptible and methicillin-resistant strains), Streptococcus pyogenes, or Streptococcus agalactiae. Zyvox has not been studied in the treatment of decubitus ulcers.
- **Uncomplicated Skin and Skin Structure Infections:** Caused by Staphylococcus aureus (methicillin-susceptible only) or Streptococcus pyogenes.
- **Community-Acquired Pneumonia:** Caused by Streptococcus pneumoniae (including multidrug resistant strains [MDRSP]*), including cases with concurrent bacteremia, or Staphylococcus aureus (methicillin-susceptible strains only).

*MDRSP refers to isolates resistant to two or more of the following antibiotics: penicillin, second-generation cephalosporins, macrolides, tetracycline, and trimethoprim/sulfamethoxazole.

NOTE: Zyvox is not indicated for the treatment of Gram-negative infections. It is critical that specific Gram-negative therapy be initiated immediately if a concomitant Gram-negative pathogen is documented or suspected.

NOTE: To reduce the development of drug-resistant bacteria and maintain the effectiveness of Zyvox and other antibacterial drugs, Zyvox should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria. When culture and susceptibility information are available, they should be considered in selecting or modifying antibacterial therapy. In the absence of such data, local epidemiology and susceptibility patterns may contribute to the empiric selection of therapy.

DOSAGE AND ADMINISTRATION

Infection	Dosage and Route of Administration		Recommended Duration of Treatment (Consecutive Days)
	Pediatric Patients (Birth through 11 Years of Age)	Adults and Adolescents (12 Years and Older)	
Complicated skin and skin structure infections	10mg/kg IV or PO every 8 hours	600mg IV or PO every 12 hours	10-14
Community-acquired pneumonia, including concurrent bacteremia			
Nosocomial pneumonia			
Vancomycin-resistant Enterococcus faecium infections, including concurrent bacteremia	10mg/kg IV or PO every 8 hours	600mg IV or PO every 12 hours	14-28
Uncomplicated skin and skin structure infections	<5 years: 10mg/kg PO every 8 hours 5-11 years: 10mg/kg PO every 12 hours	Adults: 400mg PO every 12 hours Adolescents: 600mg PO every 12 hours	10-14

- Adult patients with infection due to MRSA should be treated with Zyvox 600mg every 12 hours.

IV to PO Conversion:

Zyvox has 100% bioavailability. For patients who are being converted to the oral formulation, refer to the table below:

IV Dose	Oral Dose*
10mg/kg every 8 hours	10mg/kg every 8 hours
10mg/kg every 12 hours	10mg/kg every 12 hours
400mg every 12 hours	400mg every 12 hours
600mg every 12 hours	600mg every 12 hours

*Oral dosing using either oral suspension or tablets.

REFERENCES

1. Facts and Comparisons, St. Louis, eFacts 2010 CliniSphere Version ISBN 1-57439-036-8.
2. Zyvox. Prescribing Information. Pfizer, Inc. December 2009.
3. Stevens DL, Bisno AL, Chambers HF, Everett ED, Dellinger P, Goldstein EJC, et al. Practice Guidelines for the Diagnosis and Management of Skin and Soft-Tissue Infections. Clinical Infectious Diseases. 2005; 41:1373-406.

Revision/Review Date: 5/2010

Associated Policy: Prior Authorization of Medications 236.200

NOTE: Pharmacist reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.