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THE PRESCRIBER e-LETTER

MassHealth PHARMACY PROGRAM

Updates to Synagis

Synagis (palivizumab) is a humanized monoclonal antibody indicated for the prevention of serious lower respiratory tract disease caused by respiratory syncytial virus (RSV) in pediatric patients who are at increased risk of severe disease. It has been proven to be safe and effective in infants born at or before 35 weeks of gestation, with or without chronic lung disease (CLD) of prematurity, and with hemodynamically significant congenital heart disease (CHD). Palivizumab is dosed at 15 mg/kg and given as an intramuscular injection monthly during RSV season, defined as November through March in the United States.

Previously, five risk factors for treatment were identified by the American Academy of Pediatrics (AAP). These risk factors included exposure to environmental air pollutants, congenital airway abnormalities, severe neuromuscular disease, day care attendance, and/or school aged siblings. Current risk factors now include only the last two.

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The American Academy of Pediatrics Recommends RSV Prophylaxis in the Following Situations. Changes reflect the 2009 AAP recommendations.

- Bronchopulmonary dysplasia (BPD) or CLD, age < 24 months old at start of RSV season *plus* required medication or oxygen supplementation within last 6 months
  - Maximum of 5 doses
- hemodynamically significant CHD, age ≤ 24 months old at the start of RSV season
  - Maximum of 5 doses
- Gestational age < 28 weeks and current age < 12 months old at the start of RSV season
  - Maximum of 5 doses
- *Gestational age 29-32 weeks and current age < 6 months old at the start of RSV season
  - Maximum of 5 doses
- *Gestational age 32-34 weeks, 6 days and current age < 3 months old at the start of RSV season *plus* ≥ 1 risk factor (day care attendance, school aged siblings < 5 years of age)
  - Maximum of 3 doses

H1N1 Influenza

In previous years, the circulating seasonal influenza strains included seasonal influenza A H1N1, influenza A H3N2, and Influenza B. These strains are the target of the seasonal influenza vaccine. In April of 2009 the swine flu strain or 2009 influenza A H1N1 strain was identified. This strain requires a separate vaccination in addition to the traditional seasonal flu vaccine. According to the CDC, the 2009 H1N1 strain is currently the predominant strain of influenza circulating throughout the United States.

Antiviral medications available for influenza prophylaxis and treatment include Tamiflu (oseltamivir) and Relenza (zanamivir). Prophylaxis and treatment with antiviral medication is recommended for high risk persons, which include the following:

- Members with suspected or confirmed influenza requiring hospitalization
- Children < 2 years of age
- Members ≥ 65 years of age
- Pregnant women and women ≤ 2 weeks postpartum
- Members of any age with certain chronic medical or immunosuppressive conditions
- Members < 19 years of age receiving long-term aspirin therapy

Treatment and prophylaxis doses are typically twice daily for five days and once daily for 10 days respectively.

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MassHealth Tamiflu and Relenza Quantity Limits

To ensure clinically appropriate treatment, the following quantity limits are in effect on the MassHealth Drug List for Tamiflu and Relenza from October 1 through May 31:

- Tamiflu
  - 30 mg capsules – PA >20/month and 40 /season
  - 45 and 75 mg capsules – PA >10/month and 20/season
  - Suspension – PA >75 ml/month and 150 ml/season
- Relenza
  - PA > 20 inhalations/month and 40 inhalations/season

The Prescriber e-Letter is an update designed to enhance the transparency and efficiency of the MassHealth drug prior-authorization (PA) process and the MassHealth Drug List. Each issue will **highlight** key clinical **information and updates** to the **MassHealth Drug List**. The Prescriber E-Letter was prepared by the MassHealth Drug Utilization Review Program and the MassHealth Pharmacy Program.

Recent MassHealth Drug List Updates

Drug/Drug Class	Addition/Deletion/Change	Rationale
Otic Antibiotics	Change in PA status; **requires PA** Acetic acid/hydrocortisone (Acetasol HC) Ciprofloxacin/dexamethasone (CiproDex Otic suspension) Ciprofloxacin/hydrocortisone (Cipro HC Otic suspension) ofloxacin (Floxin Otic Singles)	There are more cost-effective alternatives available for the management of the same clinical condition including ofloxacin (5 ml and 10 ml), and neomycin/polymyxin-HC solution or suspension, which do not require prior authorization.
amphetamine salts extended release (Adderall XR)	Change in PA status; **requires PA**	Due to the availability of generic extended-release amphetamine salts, Adderall XR requires prior authorization. Generic amphetamine salts extended-release will continue to be available without PA in quantities < 60 units/month.
antipyrine/benzocaine (A/B Otic drops, Allergen, Aurodex, Auroto)	Deletion; no longer on MassHealth Drug List	MassHealth does not pay for drug products (including identical, similar, or related drug products) that the U.S. Food and Drug Administration has proposed, in a Notice of Opportunity for Hearing (NOOH), to withdraw from the market because they lack substantial evidence of effectiveness for all labeled indications.
armodafanil (Nuvigil)	Addition; **requires PA**	There are more cost-effective alternatives available for the management of the same clinical condition including cerebral stimulants such as methylphenidate and dextroamphetamine.
artemether/lumefantrine (Coartem)	Addition; **requires PA if >24 units/year**	Due to limited data to support the doses greater than those indicated by the FDA, quantities exceeding limits based on FDA-approved dosages will require prior authorization.
benzyl alcohol lotion (Ulesfia)	Addition; does not require PA	Benzyl alcohol lotion is indicated for the treatment of head lice.
besifloxacin (Besivance)	Addition; **requires PA**	There are more cost-effective alternatives available for the management of the same clinical condition including bacitracin/polymixin B preparations, ciprofloxacin solution, erythromycin ointment, gentamicin solution and ointment, ofloxacin, polymixin B/trimethoprim, sulfacetamide sodium solution and ointment, and tobramycin solution, which do not require prior authorization.
bicalutamide (Casodex)	Change in PA status; **requires PA**	Generic bicalutamide was recently FDA-approved and does not require prior authorization. Therefore, brand-name Casodex requires prior authorization.
buprenorphine HCl/naloxone HCl (Suboxone)	Change in PA status; **requires PA if quantity exceeds 16 mg/day**	Due to available data supporting long term maintenance doses of ≤ 16 mg/day, MassHealth no longer requires prior authorization for Suboxone at doses ≤ 16 mg/day.

Recent MassHealth Drug List Updates continued on next page

Recent MassHealth Drug List Updates (cont.)

Drug/Drug Class	Addition/Deletion/Change	Rationale
ciprofloxacin otic solution (Cetraxal)	Addition; **requires PA**	There are more cost-effective alternatives available for the management of the same clinical condition including ofloxacin (5 ml and 10 ml), and neomycin/polymyxin-HC solution or suspension, which do not require prior authorization.
degarelix (Firmagon)	Addition; **requires PA**	Degarelix is indicated for the treatment of advanced prostate cancer and requires PA to ensure clinically appropriate treatment.
dronedarone (Multaq)	Addition; does not require PA	Dronedarone is indicated for the treatment of atrial fibrillation or atrial flutter.
estradiol (EstroGel)	Deletion; no longer on MassHealth Drug List	MassHealth does not pay for drugs that are manufactured by companies that have not signed rebate agreements with the U.S. Secretary of Health and Human Services.
everolimus (Afinitor) 5 mg	Addition; **requires PA if >30 units/month**	Utilizing the higher tablet strength (10 mg) is less costly in comparison to multiples of the lower strength tablet. Therefore, a quantity limit has been developed.
ferumoxytol (Feraheme)	Addition; does not require PA	Ferumoxytol is indicated for the treatment of iron deficiency anemia in adults with chronic kidney disease.
fibrinogen concentrate (RiaSTAP)	Addition; does not require PA	Fibrinogen concentrate is indicated for the treatment of acute bleeding episodes in patients with congenital fibrinogen deficiency, including afibrinogenemia and hypofibrinogemia.
ibuprofen injection (Caldolor)	Addition, ^{H} symbol – inpatient use only	Ibuprofen injection is indicated for the management of mild to moderate pain, moderate to severe pain as an adjunct to opioid analgesics, and as an antipyretic in adults. This drug is only available in an inpatient hospital setting. MassHealth does not pay for this drug to be dispensed through the retail pharmacy or physician's office.
golimumab (Simponi)	Addition; **requires PA**	There are more cost-effective alternatives available for the management of the same clinical condition, including corticosteroids, methotrexate, sulfasalazine, hydroxychloroquine, azathioprine, cyclosporine, leflunomide, and thalidomide. However, thalidomide is not a first line option.
influenza virus vaccine, H1N1 (Influenza H1N1 Vaccine)	Addition; does not require PA	The influenza virus vaccine H1N1 is indicated for the prevention of H1N1influenza virus infection.
influenza virus vaccine live, intranasal (FluMist)	Change in PA status; **requires PA if >1 dose/season**	Due to limited data to support the dosing of FluMist at intervals greater than those indicated by the FDA, quantities exceeding limits based on FDA-approved dosages will require prior authorization.
Japanese encephalitis vaccine (Ixiaro)	Addition; does not require PA	The Japanese encephalitis vaccine is indicated for the prevention of Japanese encephalitis.
lamotrigine extended-release (Lamictal XR, Lamictal XR Start Kit)	Addition; **requires PA**	There are more cost-effective alternatives available for the management of the same clinical condition that do not require PA, including generic lamotrigine.

Recent MassHealth Drug List Updates continued on next page**.**

Recent MassHealth Drug List Updates (cont.)

Drug/Drug Class	Addition/Deletion/Change	Rationale
levonorgestrel (Plan B)	Change in PA status; **requires PA**	Generic levonorgestrel was recently FDA approved and does not require prior authorization. Therefore, brand-name Plan B requires prior authorization.
levonorgestrel (Plan B One Step)	Addition; does not require PA	Levonorgestrel is indicated for the prevention of pregnancy.
mesalamine delayed release tablet (Asacol HD)	Addition; does not require PA	Mesalamine delayed release tablet is indicated for the treatment of ulcerative colitis.
milnacipran (Savella)	Addition; **requires PA**	There are more cost-effective alternatives available for the management of the same clinical condition including low-dose tricyclic antidepressants, cyclobenzaprine, selective serotonin receptor inhibitors, and gabapentin, which do not require prior authorization.
prasugrel (Effient)	Addition; does not require PA	Prasugrel is indicated for the treatment of acute coronary syndromes.
saxagliptin (Onglyza)	Addition; **requires PA**	There are more cost-effective alternatives available for the management of the same clinical condition, including metformin, sulfonylureas, and thiazolidinediones, which do not require prior authorization.
sodium oxybate (Xyrem)	Addition; **requires PA**	There are more cost-effective alternatives available for the management of the same clinical condition, including tricyclic antidepressants, selective serotonin reuptake inhibitors, and venlafaxine, which do not require prior authorization. Sodium oxybate also requires PA to ensure treatment is clinically appropriate.
tacrolimus (Prograf)	Change in PA status; **requires PA**	Generic tacrolimus was recently FDA approved and does not require prior authorization. Therefore, brand-name Prograf requires prior authorization.
tadalafil (Adcirca)	Addition; **requires PA**	Tadalafil is indicated for the treatment of pulmonary hypertension and requires PA to ensure treatment is clinically appropriate.
tapentadol (Nucynta)	Addition; **requires PA**	There are more cost-effective alternatives available for the management of the same clinical condition that are available without PA, including oxycodone (< 240 mg/day), morphine IR (< 360 mg/day), codeine (< 360mg/day), and hydromorphone products (< 60 mg/day).
tolvaptan (Samsca)	Addition; **requires PA**	Tolvaptan is indicated for the treatment of hyponatremia and requires PA to ensure treatment is clinically appropriate.
ubiquinone orally disintegrating tablet (Quinzyme ODT)	Addition; **requires PA**	Ubiquinone is a more cost-effective alternative available for the management of the same clinical condition that does not require PA for members < 18 years of age.
zolpidem sublingual (Edluar)	Addition; **requires PA**	Generic zolpidem is a more cost-effective alternative available for the management of the same clinical condition available without PA in quantities ≤ 10 units/month.

Please send any **suggestions** or **comments** to: **PrescriberELetter@state.ma.us**