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THE PRESCRIBER e-LETTER

Hepatitis C Protease Inhibitors

Hepatitis C viral infection (HCV) is a major public health concern and a leading cause of chronic liver disease. Until HCV is eradicated, the goal of HCV treatment is preventing complications and reducing liver-related deaths. For years, the treatment standard for HCV was a combination of peginterferon alfa and ribavirin.

The Food and Drug Administration (FDA) has approved two direct protease inhibitors to be used in combination with peginterferon alfa and ribavirin. Incivek (telaprevir) and Victrelis (boceprevir) are approved by the FDA for the treatment of chronic hepatitis C genotype 1 infection.

In clinical trials, the HCV protease inhibitors in combination with peginterferon alfa and ribavirin improved sustained virologic response (SVR) rates compared to the standard of care (peginterferon alfa and ribavirin alone for 48 weeks). A decrease in duration of therapy was also demonstrated in some of the participants.

In order to ensure the appropriate utilization of these agents, MassHealth requires prior authorization for these products. Both Incivek (telaprevir) and Victrelis (boceprevir) were added to the MassHealth Drug List on July 25, 2011.

Incivek (telaprevir)	Victrelis (boceprevir)
Dosing and Administration	
Availability: 375 mg tablets Oral: 750 mg (2 tablets), 3 times daily (7-9 hrs apart) with food (NOT low fat) weeks 1-12	Availability: 200 mg capsules Oral: 800 mg (4 capsules), 3 times daily (7-9 hrs apart) starting week 5 (after four-week lead in with peginterferon and ribavirin)
Adverse reactions	
Rash, pruritus, anemia, nausea, diarrhea, anorectal discomfort, dysgeusia, fatigue, and vomiting	Anemia, fatigue, nausea, headache, dysgeusia

Makena (hydroxyprogesterone caproate injection)

Makena (hydroxyprogesterone caproate) represents the first drug approved by the FDA that is indicated to reduce the risk of preterm birth. It is indicated in women with a singleton pregnancy with a history of singleton spontaneous preterm birth. Hydroxyprogesterone caproate is given by a health care provider once a week via intramuscular injection into the hip. Treatment begins at week 16 (no later than week 21 of the pregnancy) and continues through week 37.

Prior to Makena (hydroxyprogesterone caproate), pharmacies used hydroxyprogesterone caproate bulk powder and castor oil [the same vehicle used in Makena (hydroxyprogesterone caproate)] to compound this product. Concerns over whether the FDA would enforce regulations over compounding a commercially available product once Makena (hydroxyprogesterone caproate) became available were answered with the FDA press release on February 3, 2011:

> "In order to support access to this important drug, at this time and under this unique situation, FDA does not intend to take enforcement action against pharmacies that compound hydroxyprogesterone caproate based on a valid prescription for an individually identified patient unless the compounded products are unsafe, of substandard quality, or are not being compounded in accordance with appropriate standards for compounding sterile products. As always, FDA may at any time revisit a decision to exercise enforcement discretion."

Due to the availability of a less costly alternative and the current FDA statement, MassHealth has required prior authorization (PA) for Makena as of July 25, 2011. The prior-authorization criteria are outlined below.

- Appropriate diagnosis (female who is currently pregnant with a singleton and has a history of spontaneous delivery prior to 37 weeks)
- Pregnancy must be between gestational weeks 16 and 21
- Documented trial of the compounded hydroxyprogesterone caproate powder
- Request is for $\leq$ 21 injections per year

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 **highlights** 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
Alzheimer's medications	Change in PA status; **the following will require PA > predetermined quantity limits as listed** Donepezil 5, 10 mg tablet (Aricept): > 30 units/month Donepezil ODT (Aricept): > 30 units/month Galantamine extended-release capsule (Razadyne ER): > 30 units/month Galantamine solution (Razadyne): > 180 mL/month Galantamine tablet (Razadyne): > 60 units/month Memantine solution (Namenda): > 360 mL/month Memantine tablets (Namenda): > 60 units/month Memantine titration pack (Namenda): > 49 units/month Rivastigmine capsule (Exelon): > 60 units/month Rivastigmine patch (Exelon): > 30 units/month Rivastigmine solution (Exelon): > 180 mL/month	Based on the findings from a recent quality assurance analysis, quantity limits have been placed on these products.
Oral contraceptives	Addition; does not require PA Ethinyl estradiol/drospirenone (Loryna) Ethinyl estradiol/norethindrone (Briellyn) Ethinyl estradiol/norethindrone/ferrous fumarate (Generess FE chewable, Zeosa chewable)	This medication is FDA-approved for use in females to prevent pregnancy.
Testosterone products	Change in PA status: **requires PA** Testosterone 1% gel (Testim, Androgel) Testosterone patch (Androderm) Testosterone intramuscular pellet (Testopel)	There are more cost-effective alternatives available without prior authorization for males, including testosterone cypionate and testosterone enanthate injection.
Azilsartan (Edarbi)	Addition; **requires PA**	There are more cost-effective alternatives available without prior authorization, including generic ACE inhibitors.
Belimumab (Benlysta)	Addition; **requires PA**	This medication is FDA-approved for the treatment of adult patients with active, autoantibody-positive, systemic lupus erythematosus (SLE) who are receiving standard therapy. There are more cost-effective alternatives available without prior authorization, including azathioprine, methotrexate, and mycophenolate.
Benzyl alcohol lotion (Ulesfia)	Change in PA status; **requires PA**	There are other alternatives available without prior authorization, including permethrin, pyrethrin/piperonyl butoxide and malathion.
Boceprevir (Victrelis)	Addition; **requires PA**	This medication is FDA-approved for the treatment of chronic hepatitis C genotype 1 infection, in combination with peginterferon alfa and ribavirin, in adult patients with compensated liver disease, including cirrhosis, who are previously untreated or who have failed previous interferon and ribavirin therapy. It will require prior authorization to ensure appropriate utilization.

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

Recent MassHealth Drug List Updates (cont.)

Drug/Drug Class	Addition/Deletion/Change	Rationale
Chlorpheniramine/ pseudoephedrine (Deconamine)	Deletion; no longer on MassHealth Drug List	This drug has been removed from the MassHealth Drug List because it is not approved by the FDA.
Diltiazem (Matzim LA)	Addition; does not require PA	This medication is FDA-approved for the treatment of hypertension and the management of chronic stable angina.
Donepezil 23 mg (Aricept)	Change in PA status; **requires PA**	This medication requires prior authorization to ensure proper dosing as recommended in the prescribing information.
Fenofibrate (Fenoglide)	Deletion; no longer on MassHealth Drug List	The following drug has been deleted from the 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.
Fluorouracil 5% cream (Efudex)	Change in PA status; **requires PA**	There are more cost-effective alternatives available without prior authorization, including fluorouracil 5% solution.
Gatifloxacin 0.3% ophthalmic solution (Zymar)	Deletion; no longer on MassHealth Drug List	This product has been removed from the MassHealth Drug List because it has been discontinued by the manufacturer.
Granisetron solution (Kytril)	Deletion; no longer on MassHealth Drug List	This product has been removed from the MassHealth Drug List because it has been discontinued by the manufacturer.
Hydroxyprogesterone caproate injection (Makena)	Addition; **requires PA**	There are more cost-effective alternatives available without prior authorization, including compounded hydroxyprogesterone caproate.
Methylphenidate ER (Concerta)	Change in PA status; **requires PA**	There are more cost-effective alternatives available without prior authorization, including the authorized generic methylphenidate ER for up to 60 units/month.
Morphine/naloxone (Embeda)	Deletion; no longer on MassHealth Drug List	This product has been removed from the MassHealth Drug List because it has been discontinued by the manufacturer.
Podofilox gel (Condylox)	Change in PA status; **requires PA**	There are more cost-effective alternatives available without prior authorization, including podofilox solution.
Spinosad (Natroba)	Addition; **requires PA**	There are other alternatives available without prior authorization, including permethrin, pyrethrin/piperonyl butoxide, and malathion.
Sumatriptan injection (Sumavel DosePro)	Addition; **requires PA**	There are more cost-effective alternatives available without prior authorization, including sumatriptan tablets for up to 9 units/month.

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Recent MassHealth Drug List Updates (cont.)

Drug/Drug Class	Addition/Deletion/Change	Rationale
Telaprevir (Incivek)	Addition; **requires PA**	This medication is FDA-approved for the treatment of chronic hepatitis C genotype 1 infection, in combination with peginterferon alfa and ribavirin, in adult patients with compensated liver disease, including cirrhosis, who are treatment naïve or who have been previously treated with interferon-based treatment, including prior null responders, partial responders, and relapsers. It requires prior authorization to ensure appropriate utilization.
Testosterone 2% solution (Axiron)	Addition; **requires PA**	There are more cost-effective alternatives available without prior authorization for males, including testosterone cypionate and testosterone enanthate injection.
Testosterone 10 mg/actuation pump (FORTESTA)	Addition; **requires PA**	There are more cost-effective alternatives available without prior authorization for males, including testosterone cypionate and testosterone enanthate injection.

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