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THE PRESCRIBER e-LETTER

Egrifta (tesamorelin)

Egrifta® (tesamorelin) is approved by the U.S. Food and Drug Administration (FDA) for the reduction of excess abdominal fat in human immunodeficiency virus (HIV)-infected patients with lipodystrophy. Tesamorelin is a growth hormone releasing factor analog that stimulates pituitary production and release of growth hormone, which is both anabolic and lipolytic. It is the first FDA-approved therapy for central fat accumulation in HIV-infected patients.[1]

The term "HIV-associated lipodystrophy" describes two types of abnormal fat distribution in HIV-infected patients: fat accumulation and lipoatrophy (subcutaneous fat loss), both of which are thought to be the side effects of antiretroviral therapy. This abnormal fat distribution is often associated with metabolic abnormalities such as dyslipidemia and insulin resistance.[2]

There is currently no consensus on whether HIV-associated central fat accumulation should be treated in patients without the presence of other metabolic risk factors. Treatment options for HIV-associated central fat accumulation are limited. Modification in antiretroviral regimen can reduce visceral adipose tissue but may not be realistic in clinical practice. Exercise and metformin may be effective but can also potentially worsen subcutaneous fat loss in patients with lipoatrophy.[3]

Egrifta® (tesamorelin) was added to the MassHealth drug list requiring prior authorization effective **October 31, 2016** requiring PA for tesamorelin for the treatment of HIV-associated lipodystrophy.

Table 1: Tesamorelin Agents PA Status

Drugs that require PA	No PA
Egrifta® (tesamorelin)	N/A

1. Approval of Egrifta (tesamorelin) to treat lipodystrophy [press release on the internet]. Rockville (MD): Food and Drug Administration (US): 2010 Nov 10 [cited 2016 Nov 4]. Available from: http://www.fda.gov/ForConsumers/ByAudience/ForPatientAdvocates/HIVandAIDSActivities/ucm233573.htm.
2. Wanke CA. Epidemiology, clinical manifestations, and diagnosis of HIV-associated lipodystrophy. In: Basow DS (Ed). UpToDate [database on the internet]. Waltham (MA): UpToDate; 2016 [cited 2016 Nov 4]. Available from: http://www.utdol.com/utd/index.do.
3. Schambelan M, Benson CA, Carr A, Currier JS, Dube MP, Gerber JG, et al. Management of metabolic complications associated with antiretroviral therapy for HIV-1 infection: recommendations of an International AIDS Society-USA Panel. J Acquir Immune Defic Syndr. 2002 Nov 1;31(3):257-75.

Lipid-Lowering Agents

Elevated lipid levels are a risk factor for cardiovascular disease. The principles of treating hypercholesterolemia, established in 2002 by the National Cholesterol Education Program's (NCEP) Adult Treatment Panel 3 (ATP III) changed significantly with the release of cholesterol treatment guidelines by the American Heart Association (AHA) and American College of Cardiology (ACC) in 2013.[1, 2]

Available treatment options include statins, ezetimibe (Zetia®), omega 3-acid ethyl esters, fenofibrate products, niacin, and proprotein convertase subtilisin kexin 9 (PCSK9) inhibitors.

Statins are competitive inhibitors of HMG CoA reductase, the rate-limiting step in cholesterol biosynthesis.[1] Various statins are available and all are effective at lowering LDL-C levels; however, they have different degrees of LDL-C lowering potency.[1, 2]

Effective **October 31, 2016**, the prior authorization process for lipid lowering agents was modified to remove the requirement of PA for Crestor® (rosuvastatin) following the availability of multi-source generics. Prior authorization status for rosuvastatin is included below:

Table 2: Lipid Lowering Agents PA Status: Rosuvastatin

Drugs that require PA	No PA
Crestor® (rosuvastatin 5 mg, 10 mg, 20 mg) **> 45 units/month***	Crestor® # (rosuvastatin 5 mg, 10 mg, 20 mg) **≤ 45 units/month**
Crestor® (rosuvastatin 40 mg) **> 30 units/month***	Crestor® # (rosuvastatin 40 mg) **≤ 30 units/month**

*Available as an A-rated generic, both brand and generic require PA.

1 Third report of the National Cholesterol Education Program (NCEP) Expert Panel on detection, evaluation, and treatment of high blood cholesterol in adults (Adult Treatment Panel III). Circulation. 2002 Dec 17;106(25):3143-421.

2. Stone NJ, Robinson J, Lichtenstein AH, Bairey Merz CN, Lloyd-Jones DM, Blum CB et al. 2013 ACC/AHA Guideline on the Treatment of Blood Cholesterol to Reduce Atherosclerotic Cardiovascular Risk in Adults: A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines. J Am Coll Cardiol. 2013 Nov 7. pii: S0735-1097(13)06028-2. doi: 10.1016/j.jacc.2013.11.002.

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
Antidepressants	Change in PA status: does not require PA duloxetine 20 mg, 30 mg, 60 mg (Cymbalta®#) – **PA < 6 years** fluoxetine 40 mg capsule (Prozac®#) – **PA < 6 years**	Based on a decrease in cost, MassHealth has determined that these agents will not require a PA within age limits.
Antihemophilia agents	Addition: does not require PA antihemophilic factor, recombinant, single chain (Afstyla®) Von Willebrand factor, recombinant (Vonvendi®)	MassHealth has determined that these agents will not require PA.
Cardiovascular agents	Addition: **requires PA** nebivolol/valsartan (Byvalson®) lisinopril solution (Qbrelis®)	Byvalson® is a new combination antihypertensive product consisting of a beta-blocker and angiotensin II receptor blocker. Qbrelis® is a new liquid formulation of lisinopril. Based on the availability of less costly alternative formulations, MassHealth has determined these agents will require PA.
	Change in PA status: does not require PA dofetilide (Tikosyn®#)	Based on the availability of a new FDA "A"-rated generic for Tikosyn®, MassHealth has determined that generic dofetilide will not require a PA.
	Deletion: no longer on MassHealth Drug List amlodipine/aliskiren/hydrochlorothiazide (Amturnide®) amlodipine/aliskiren (Tekamlo®)	These drugs have been removed from the MassHealth Drug List because they have been discontinued by the manufacturer.
Cerebral Stimulants and ADHD Medications	Change in PA status: does not require PA guanfacine extended-release (Intuniv®#) – **PA < 3 years**	Based on a decrease in cost, MassHealth has determined that this agent will not require a PA within age limits.
	Change in PA status: removed from Brand Name Preferred Over Generic List amphetamine salts extended-release (Adderall XR®) – **PA < 3 years and PA > 60 units/month**	Based on a decrease in cost of the generic product, MassHealth has determined at this agent will no longer be included on the Brand Name Preferred Over Generic List.
Gastrointestinal agents	Change in PA status: **requires PA** famotidine suspension (Pepcid®)	Based on an increase in cost and the availability of less costly alternatives, MassHealth has determined that this agent will require PA.
	Change in PA status: does not require PA omeprazole 40 mg – **PA > 60 units/month**	Based on a decrease in cost, MassHealth has determined that this agent will not require a PA within quantity limits.
	Deletion: no longer on MassHealth Drug List esomeprazole strontium bismuth subsalicylate/tetracycline/metronidazole (Helidac®) omeprazole 10 mg (Prilosec®) omeprazole 20 mg (Prilosec®) ranitidine, effervescent tablet (Zantac Efferdose®)	These drugs have been removed from the MassHealth Drug List because they have been discontinued by the manufacturer.

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Antihemophilia agents	Addition: does not require PA antihemophilic factor, recombinant, single chain (Afstyla®) Von Willebrand factor, recombinant (Vonvendi®)	MassHealth has determined that these agents will not require PA.
Cardiovascular agents	Addition: **requires PA** nebivolol/valsartan (Byvalson®) lisinopril solution (Qbrelis®)	Byvalson® is a new combination antihypertensive product consisting of a beta-blocker and angiotensin II receptor blocker. Qbrelis® is a new liquid formulation of lisinopril. Based on the availability of less costly alternative formulations, MassHealth has determined these agents will require PA.
	Change in PA status: does not require PA dofetilide (Tikosyn®#)	Based on the availability of a new FDA "A"-rated generic for Tikosyn®, MassHealth has determined that generic dofetilide will not require a PA.
	Deletion: no longer on MassHealth Drug List amlodipine/aliskiren/hydrochlorothiazide (Amturnide®) amlodipine/aliskiren (Tekamlo®)	These drugs have been removed from the MassHealth Drug List because they have been discontinued by the manufacturer.
Cerebral Stimulants and ADHD Medications	Change in PA status: does not require PA guanfacine extended-release (Intuniv®#) – **PA < 3 years**	Based on a decrease in cost, MassHealth has determined that this agent will not require a PA within age limits.
	Change in PA status: removed from Brand Name Preferred Over Generic List amphetamine salts extended-release (Adderall XR®) – **PA < 3 years and PA > 60 units/month**	Based on a decrease in cost of the generic product, MassHealth has determined at this agent will no longer be included on the Brand Name Preferred Over Generic List.
Gastrointestinal agents	Change in PA status: **requires PA** famotidine suspension (Pepcid®)	Based on an increase in cost and the availability of less costly alternatives, MassHealth has determined that this agent will require PA.
	Change in PA status: does not require PA omeprazole 40 mg – **PA > 60 units/month**	Based on a decrease in cost, MassHealth has determined that this agent will not require a PA within quantity limits.
	Deletion: no longer on MassHealth Drug List esomeprazole strontium bismuth subsalicylate/tetracycline/metronidazole (Helidac®) omeprazole 10 mg (Prilosec®) omeprazole 20 mg (Prilosec®) ranitidine, effervescent tablet (Zantac Efferdose®)	These drugs have been removed from the MassHealth Drug List because they have been discontinued by the manufacturer.

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Hepatitis Antiviral Agents	Addition: **requires PA** dasabuvir/ombitasvir/paritaprevir/ritonavir extended-release (Viekira XR®)	Based on high cost, opportunities to manage the duration of therapy and off-label use, and to promote utilization of the preferred products, MassHealth has determined this agent will require a PA.
	Change in PA status: added to Supplemental Rebate/Preferred Drug List sofosbuvir/velpatasvir (Epclusa®) PD	MassHealth has either entered into a supplemental rebate agreement with drug manufacturers or designated a particular drug as preferred based on net costs to MassHealth, allowing MassHealth the ability to provide coverage of medications at the lowest possible costs.
Lipid Lowering Agents	Change in PA status: does not require PA rosuvastatin 5 mg, 10 mg, 20 mg (Crestor®#) – **PA > 45 units/month** rosuvastatin 40 mg (Crestor®#) **– PA > 30 units/month**	Based on the availability of multi-source FDA "A"-rated generics for Crestor®, MassHealth has determined that generic rosuvastatin will not require PA within quantity limits.
Opioids and Analgesics	Addition: **requires PA** butalbital 25 mg/acetaminophen 325 mg tablet oxycodone extended-release capsule (Xtampza ER®)	Oxycodone extended-release is indicated for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate. Based on the availability of less costly alternatives, MassHealth has determined these agents will require PA.
	Change in PA status: added to Brand Name Preferred Over Generic List oxycodone extended-release tablet (Oxycontin®) BP	Based on the net cost of the brand name drug adjusted for rebates being lower than the net cost of the generic equivalents, MassHealth has determined that this agent will be added to the Brand Name Preferred Over Generic List.
Phosphate Binding Agents	Change in PA status: does not require PA ferric citrate (Auryxia®) lanthanum (Fosrenol®) sucroferric oxyhydroxide (Velphoro®)	Based on a decrease in cost, MassHealth has determined that these agents will no longer require PA.
Topical Anesthetics	Change in PA status**: requires PA** lidocaine ointment	Based on an increase in cost and the availability of less costly alternatives, MassHealth has determined that this agent will require PA.
	Change in PA status: does not require PA lidocaine patch (Lidoderm®#) – **PA > 90 patches/month**	Based on a decrease in cost, MassHealth has determined that this agent will not require PA within quantity limits.
	Deletion: no longer on MassHealth Drug List lidocaine (Xylocaine®#)	This drug has been removed from the MassHealth Drug List because it has been discontinued by the manufacturer.
Triptans	Addition: **requires PA** sumatriptan nasal powder (Onzetra Xsail®) sumatriptan injection (Zembrace Symtouch®)	Zembrace Symtouch® is a new drug-device combination product indicated for the treatment of acute migraine with or without aura in adults who are inadequately managed with existing treatment regimens. Onzetra Xsail® is a new breath powered nasal delivery system indicated for the treatment of acute migraine with or without aura in adults. Based on the high cost of these agents compared to the oral formulations MassHealth has determined these agents will require PA.

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Vaccines	Addition: does not require PA cholera vaccine, live, oral (Vaxchora®)	MassHealth has determined that this agent will not require PA.
	Deletion: no longer on MassHealth Drug List japanese encephalitis vaccine (Je-Vax®) BCG live, intravesical (Tice BCG®) diphtheria/tetanus toxoids/acellular pertussis vaccine (Tripedia®)	These drugs have been removed from the MassHealth Drug List because they have been discontinued by the manufacturer.
atezolizumab (Tecentriq®)	Addition: **requires PA**	Atezolizumab is indicated for the treatment of patients with locally advanced or metastatic urothelial carcinoma (UC) who have disease progression during or following platinum-containing chemotherapy or have disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy. Based on high cost and potential for off-label use, MassHealth has determined this agent will require PA.
brivaracetam solution (Briviact®)	Addition: **requires PA**	Brivaracetam is indicated for the adjunctive treatment of partial-onset seizures in patients 16 years of age and older with epilepsy. Based on the availability of well-established, less costly alternatives for the adjunctive treatment of partial-onset seizures, MassHealth has determined this agent will require PA.
buprenorphine implant (Probuphine®)^	Addition: **requires PA**	Implantable buprenorphine is indicated for the maintenance treatment of opioid dependence in patients who have achieved and sustained prolonged clinical stability on low-to-moderate doses of a transmucosal buprenorphine-containing product. Based on the specific indication and high cost of therapy, MassHealth has determined this agent will require PA.
cabozantinib (Cabometyx®)	Addition: **requires PA**	Cabozantinib is indicated for the treatment of patients with advanced renal cell carcinoma who have received prior antiangiogenic therapy. Based on the specific indication, NCCN guidelines listing cabozantinib as a category 1 recommendation as targeted therapy after antiangiogenic therapy, and high cost of therapy, MassHealth has determined this agent will require PA.
Calcitriol (Calcijex®)	Deletion: no longer on MassHealth Drug List	This drug has been removed from the MassHealth Drug List because it has been discontinued by the manufacturer.
daclizumab (Zinbryta®)	Addition: **requires PA**	Daclizumab is a humanized monoclonal antibody indicated for the treatment of relapsing remitting multiple sclerosis (MS). Based on the availability of well-established, less costly alternatives MassHealth has determined this agent will require PA.
ethinyl estradiol/norelgestromin (Ortho Evra®#)	Deletion: no longer on MassHealth Drug List	This drug has been removed from the MassHealth Drug List because it has been discontinued by the manufacturer.
hyaluronate (Gelsyn®)	Addition: **requires PA**	Based on the availability of less costly alternatives, MassHealth has determined this agent will require PA.
insulin human inhalation powder (Afrezza®)	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.

Recent MassHealth Drug List Updates

Drug/Drug Class	Addition/Deletion/Change	Rationale
levothyroxine (Levo-T® #)	Addition: does not require PA	MassHealth has determined that this agent will not require PA.
Nilutamide (Nilandron® #)	Change in PA status: does not require PA	Based on the availability of a new FDA "A"-rated generic for Nilandron®, MassHealth has determined that generic nilutamide will not require a PA.
obeticholic acid (Ocaliva®)	Addition: **requires PA**	Obeticholic acid is a once-daily agonist at the farnesoid X receptor (FXR) indicated for the treatment of primary biliary cholangitis (PBC) in combination with ursodeoxycholic acid (UDCA) in adults with an inadequate response to UDCA, or as monotherapy in adults unable to tolerate UDCA. Based on high cost to, lack of long-term clinical outcomes, and potential for off-label use, MassHealth has determined this agent will require PA.
pimavanserin (Nuplazid®)	Addition: **requires PA**	Pimavanserin is an atypical antipsychotic indicated for the treatment of hallucinations and delusions associated with Parkinson's disease psychosis (PDP). Based on the specific indication and availability of less costly alternative, MassHealth has determined this agent will require PA.
polyethylene glycol (Miralax®#)	Deletion: no longer on MassHealth Drug List	This drug has been removed from the MassHealth Drug List because it has been discontinued by the manufacturer.
raltegravir (Isentress®)	Change in PA status: does not require PA	Based on consensus guidelines recommending raltegravir containing regimens as preferred for postexposure prophylaxis and medical necessity to initiate prophylaxis in a timely manner, MassHealth has determined this agent will not require PA.
reslizumab (Cinqair®)	Addition: **requires PA**	Reslizumab is a humanized interleukin-5 (IL-5) antagonist monoclonal antibody indicated as add-on treatment for adults aged 18 years and older with severe asthma and elevated eosinophil levels. Based on high cost and currently undefined role of this agent in the current consensus guidelines, MassHealth has determined this agent will require PA.
sodium phenylacetate/sodium benzoate (Ammonul®#)	Change in PA status: does not require PA	Based on the availability of a new FDA "A"-rated generic for Ammonul®, MassHealth has determined that generic sodium phenylacetate/sodium benzoate will not require a PA.
tacrolimus extended-release tablet (Envarsus XR®)	Change in PA status: does not require PA	Based on limited use and similar price to alternative agents, MassHealth has determined this agent will not require PA.
venetoclax (Venclexta®)	Addition: **requires PA**	Venetoclax indicated for the treatment of patients with chronic lymphocytic leukemia (CLL) with 17p deletion, as detected by an FDA approved test, who have received at least one prior therapy. Based on the specific indication of venetoclax, NCCN guidelines including venetoclax as the second regimen listed in order of preference, high cost and potential for off-label use, MassHealth has determined this agent will require PA.