West Virginia Medicaid
Pharmacy Solutions

JUNE, 2019

West Virginia Medicaid Pharmacy Department

https://dhhr.wv.gov/bms/BMS%20Pharmacy

Provider Services

888-483-0793
888-483-0801 (Pharmacy)
304-348-3360
Monday – Friday
8:00 am until 5:00 pm

Pharmacy Help Desk& Pharmacy Prior Authorization (Rational Drug Therapy Program)

800-847-3859 (Phone)
800-531-7787 (Fax)
Monday – Saturday
8:30 am until 9:00 pm
Sunday 12:00 pm until 6:00 pm

Member Services

888-483-0797
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Monday – Friday
8:00 am until 5:00 pm

Preferred Drug List

For a copy of the most recent preferred drug list, visit:
https://dhhr.wv.gov/bms/BMS%20Pharmacy/Pages/Preferred-Drug-List.aspx

State Maximum Allowable Cost (SMAC)

SMAC Review Form:
https://dhhr.wv.gov/bms/BMS%20Pharmacy/SMAC/Pages/default.aspx
Please refer questions to Change Healthcare at 1-855-389-9504 or e-mail to
PBA_WVSMAC@changehealthcare.com

Psoriasis: Treatment Update

Psoriasis is a chronic, inflammatory multisystem disease that affects up to 3.2% of the US population. While the symptoms of psoriasis are visible on the skin, other physical and mental issues also occur and can significantly impact a patient's quality of life. Until 2004, treatment options for psoriasis were limited to vitamin D_3 derivatives, retinoids, steroids, etc. In 2004, the FDA approved the first biologic (etanercept) for the treatment of Psoriasis. Today there are 10 FDA approved biologics for the treatment of psoriasis with one biologic pending FDA approval. With the new advancements, the American Academy of Dermatology (AAD) and the National Psoriasis Foundation (NPF) recently released new guidelines of best practices to aid physicians in the treatment of psoriasis.

For a full report on the guidelines got to: https://www.jaad.org/article/S0190-9622(18)33001-9/fulltext

Biologic	Trade Name	FDA Approval
Etanercept	Enbrel	FDA approval on April 30, 2004
Infliximab	Remicade/Renflexis	FDA approval on September 27, 2006
Adalimumab	Humira	FDA approval on January 22, 2008
Certolizumab	Cimzia	FDA approval on May 27, 2018
Ustekinumab	Stelara	FDA approval on September 25, 2009
Secukinumab	Cosentyx	FDA approval on January 21, 2015
Ixekizumab	Taltz	FDA approval on March 22, 2016
Brodalumab	Siliq	FDA approval on February 15, 2017
Guselkumab	Tremfya	FDA approval on July 13, 2017
Tildrakizumab	Ilumya	FDA approval on March 21, 2018
Risankizumab	Skyrizi	FDA approval April 23, 2019*
Skyrizi (risankizumab) was not FDA approved when the new guidelines were released.		

The new guidelines were created based on the input from a working group of psoriasis experts including dermatologists, a rheumatologist, a cardiologist and a patient advocate. Their recommendations were developed on the basis of best available evidence. The strength of evidence was ranked as:

A. recommendation based on consistent and good quality patient-oriented evidence
B. recommendation based on inconsistent or limited-quality patient-oriented evidence
C. recommendation based on consensus, opinion, case studies, or disease-oriented evidence.

In situations where documented evidence-based data are not available, they utilized expert opinion to generate clinical recommendations or opted not to issue a recommendation.

The table that follows compares the indication and strength of recommendation for each biologic agent:

Psoriasis: Treatment Update (2nd page)

INDICATION	STRENGTH OF RECOMMENDATION								
Recommended as a monotherapy treatment option in adult patients with:	etanercept	infliximab	adalimumab	usetekinumab	secukinumab	ixekizumab	brodalumab	guselkumab	tildrakizumab
moderate-to-severe plaque psoriasis	A	A	A	A	A	A	A	A	A
moderate-to-severe plaque psoriasis affecting the scalp	A	B	B	C	B	B		A	
moderate-to-severe plaque psoriasis affecting the nails	A	B	A	B	A	B		A	
other subtypes (pustular or erythrodermic) of moderate-to-severe plaque psoriasis	B	C	B	C	A				
plaque psoriasis of any severity when associated with psoriatic arthritis significant psoriatic arthritis	A	A	A	A	A	A			
moderate-to-severe plaque psoriasis affecting the palms and soles (plaque-type palmoplantar psoriasis)		B	A	B	A				
moderate-to-severe palmoplantar pustulosis					B			A	
erythrodermic psoriasis					C	B			
generalized pustular psoriasis						B	B		
ROUTE OF ADMINISTRATION	SC	IV	SC	SC	SC	SC	SC	SC	SC

A brief summary of each biologic's dosing and efficacy is presented below.

Etanercept is a recombinant human tumor necrosis factor (TNF) receptor. The approved dosing is 50 mg subcutaneously (SC) twice weekly for 12 weeks followed by 50 mg once weekly thereafter. Etanercept 50 mg twice weekly and 50 mg once weekly have been shown to be effective in treating moderate to severe psoriasis when compared to placebo, methotrexate other biologics.

A pooled analysis based on phase II and phase III clinical trials showed 49% of patients receiving etanercept 50 mg twice weekly and 33% receiving 50 mg weekly achieved a PASI 75 after 12 weeks vs 3% for placebo. Another study compared etanercept with tildrakizumab and placebo. After 12 weeks, 66% of patients receiving tildrakizumab 200 mg achieved a PASI 75 vs 61% in the tildrakizumab 100 mg group, 48% in etanercept group and 6% in placebo group.

See Prescribing Information for more info: https://www.pi.amgen.com/~/media/amgen/repositorysites/pi-amgen-com/enbrel/enbrel_pi.pdf

Infliximab is a chimeric monoclonal antibody. Infliximab is administered 5 mg/kg intravenously at weeks 0, 2, and 6, and every 8 weeks thereafter. In a pivotal phase III trial, 75.5% of patients on infliximab 5 mg/kg and 70.3% on infliximab 3 mg/kg achieved a PASI 75 vs 1.9% of placebo patients.

See Prescribing Information for more info: https://www.merck.com/product/usa/pi_circulars/r/renflexis/renflexis_pi.pdf

Adalimumab is a human anti-TNF monoclonal antibody. Dosing for adalimumab is 80 mg SC initially, 40 mg SC the next week and then every 2 weeks thereafter. A phase III adalimumab trial found 71% of patients on adalimumab with a PASI 75 vs 7% of patients on placebo at week 16.

See Prescribing Information for more info: https://www.rxabbvie.com/pdf/humira.pdf

Certolizumab is a humanized antigen-binding fragment of a monoclonal antibody. Certolizumab is dosed 400 mg SC every other week. In a phase II trial, 83% of patients on certolizumab 400 mg achieved a PASI 75 vs 7% of patients on placebo.

See Prescribing Information for more info: https://www.cimzia.com/sites/default/files/docs/CIMZIA_full_prescribing_information_1.pdf

Ustekinumab is a human monoclonal antibody. Ustekinumab is dosed weight based. For adult patients weighing 100 kg or less is 45 mg SC initially and 4 weeks thereafter followed by 45 mg SC every 12 weeks. For patients weighing over 100 kg, the dosage is 90 mg SC initially, 4 weeks later and then every 12 weeks. See Prescribing Information for weight based dosing in patients under 18. The efficacy of ustekinumab was established in multiple clinical trials. In one 12-week trial (PHOENIX 1), 67.1% of patients on 90 mg ustekinumab vs 3.1% of patients on placebo achieved a PASI 75.

See Prescribing Information for more info: http://www.janssenlabels.com/package-insert/product-monograph/prescribing-information/STELARA-pi.pdf

Secukinumab is a human IgG1 monoclonal antibody. The initial dose is 300 mg SC at weeks 0, 1, 2, 3 and 4 followed by 300 mg every 4 weeks. In the ERASURE trial, 81.6% of patients on secukinumab 300 mg, 71.6% on secukinumab 150 mg vs 4.5% on placebo achieved PASI 75 at week 12. The FIXTURE trial compared secukinumab vs etanercept. In this trial, 77.1% of patients on secukinumab 300 mg, 67% on secukinumab 150 mg achieved PASI 75 vs 44% of patients on etanercept and 4.9% of the placebo group. In the CLEAR trial, 79% of patients on secukinumab achieved PASI 90 at week 16 vs 57.6% of patients receiving ustekinumab.

See Prescribing Information for more info: https://www.pharma.us.novartis.com/sites/www.pharma.us.novartis.com/files/cosentyx.pdf

Ixekizumab is a humanized IgG4 monoclonal antibody. The dose is 160 mg SC initially followed by 80 mg at weeks 2, 4, 6, 8, 10 and 12. The maintenance dose after 12 weeks is 80 mg every 4 weeks. The efficacy of ixekizumab vs placebo was established in multiple clinical trials. In one phase III trial (UNCOVER-3), 84.2% of patients on 80 mg of ixekizumab vs 53.4% of patients on etancerpt and 7.3% of placebo patients achieved PASI 75.

See Prescribing Information for more info: http://uspl.lilly.com/taltz/taltz.html#pi

Brodalumab is a human monoclonal antibody. The dose is 210 mg SC on weeks 0, 1 and 2 followed by 210 mg every 2 weeks. In two phase III trials, 86% and 67% of patients on 210 mg of brodalumab vs 8% and 6% of placebo patients achieved PASI 75 at week 12.

See Prescribing Information for more info: https://www.bauschhealth.com/Portals/25/Pdf/PI/Siliq-pi.pdf

Guselkumab is a human IgG1 lambda monoclonal antibody. The dose for guselkumab is 100 mg at week 0, 4 and every 8 weeks thereafter. A phase III trial (VOYAGE 2) compared guselkumab with adalimumab and placebo. At week 16, 70% of guselkumab patients achieved PASI 90 vs 46.8% for adalimumab and 2.4% for placebo.

See Prescribing Information for more info: http://www.janssenlabels.com/package-insert/product-monograph/prescribing-information/TREMFYA-pi.pdf

Tildrakizumab is a humanized IgG1 monoclonal antibody. The dose is 100 mg SC (physician administered) at week 0, week 4 and every 12 weeks thereafter. In a phase III trial (resurface 2), 66% of patients on tildrakizumab 200 mg and 61% on 100 mg achieved PASI 75 vs 48% on etanercept and 6% on placebo.

See Prescribing Information for more info: https://www.ilumya.com/pdfs/Sun_Pharma_ILUMYA_US_Prescribing_Information.pdf

Risankizumab (FDA approval was still pending when the guidelines were updated) is a humanized IgG1 monoclonal antibody. In one clinical trial, 77% of patients on risankizumab (pooled groups of 90 mg and 180 mg dosing) vs 40% of patients on ustekinumab achieved PASI 90.
The guidelines also illustrate the role of patient preferences and patient education. Factors that may influence patient preference include but aren't limited to: disease severity, dosing schedule/frequency, cost and route of administration. These guidelines are recommendations for the use of biologics in the treatment of psoriasis and did not include psoriatic arthritis.

See Prescribing Information for more info: https://www.rxabbvie.com/pdf/skyrizi_pi.pdf

Upcoming PDL Changes

The following changes will be made to the Preferred Drug List (PDL), effective change date (7/1/2019), pending recommendation and/or approval by the P&T Committee, BMS, and Secretary of DHHR.

For a comprehensive PDL, refer to: https://dhhr.wv.gov/bms/BMS%20Pharmacy/Pages/Preferred-Drug-List.aspx

NEW PREFERRED DRUGS	
THERAPEUTIC CLASS	**RECOMMENDED for PREFERRED STATUS**
ACNE AGENTS, TOPICAL	tretinoin cream and gel
ERYTHROPOIESIS STIMULATING PROTEINS	RETACRIT (epoetin alfa)
PITUITARY SUPPRESSIVE AGENTS, LHRH	LUPANETA (leuprolide)
PITUITARY SUPPRESSIVE AGENTS, LHRH	LUPRON DEPOT KIT (leuprolide)
PITUITARY SUPPRESSIVE AGENTS, LHRH	LUPRON DEPOT-PED KIT (leuprolide)
PITUITARY SUPPRESSIVE AGENTS, LHRH	ORILISSA (elagolix)
PITUITARY SUPPRESSIVE AGENTS, LHRH	SYNAREL (nafarelin)
PITUITARY SUPPRESSIVE AGENTS, LHRH	TRELSTAR (triptorelin)
PITUITARY SUPPRESSIVE AGENTS, LHRH	TRIPTODUR (triptorelin)
PITUITARY SUPPRESSIVE AGENTS, LHRH	VANTAS (histrelin)
PITUITARY SUPPRESSIVE AGENTS, LHRH	ZOLADEX (goserelin)

NEW NON-PREFERRED DRUGS	
THERAPEUTIC CLASS	**RECOMMENDED for NON-PREFERRED STATUS**
ACNE AGENTS, TOPICAL	ALTRENO LOTION (tretinoin)
ACNE AGENTS, TOPICAL	PLIXDA SOLUTION (adapalene)
ACNE AGENTS, TOPICAL	RETIN-A CREAM AND GEL (tretinoin)
ANALGESICS, NARCOTIC SHORT ACTING (Non-parenteral)	ROXYBOND (oxycodone)
ANESTHETICS, TOPICAL	LIDOZION LOTION (lidocaine)
ANTICONVULSANTS: CANNABINOIDS	EPIDIOLEX SOLUTION (cannabidiol)
ANTIHEMOPHILIA FACTOR AGENTS	JIVI
ANTIMIGRAINE AGENTS, CGRP INHIBITORS	AIMOVIG (erenumab)
ANTIMIGRAINE AGENTS, CGRP INHIBITORS	AJOVY (fremanezumab)
ANTIMIGRAINE AGENTS, CGRP INHIBITORS	EMGALITY (galcanezumab)
ANTIPSYCHOTICS, ATYPICAL	PERSERIS (risperidone)
ANTIRETROVIRALS: SINGLE TABLET REGIMENS	DELSTRIGO (doravirine/lamivudine/tenofovir df)
ANTIRETROVIRALS: SINGLE TABLET REGIMENS	ATRIPLA (efavirenz/emtricitabine/tenofovir df

NEW NON-PREFERRED DRUGS	
THERAPEUTIC CLASS	**RECOMMENDED for NON-PREFERRED STATUS**
ANTIRETROVIRALS: SINGLE TABLET REGIMENS	PIFELTRO (doravirine)
ANTIRETROVIRALS: SINGLE TABLET REGIMENS	SYMTUZA (darunavir/cobicistat/emtricitabine/tenofovir alafenamide)
ANTIVIRALS, ORAL	XOFLUZA (baloxavir)
CYTOKINE & CAM ANTAGONISTS	ILUMYA (tildrakizumab)
CYTOKINE & CAM ANTAGONISTS	OLUMIANT (baricitinib)
ERYTHROPOIESIS STIMULATING PROTEINS	PROCRIT (rHuEPO)
NEUROPATHIC PAIN	ZTLIDO PATCH (lidocaine)
OPIATE DEPENDENCE TREATMENTS	LUCEMYRA (lofexidine)
PITUITARY SUPPRESSIVE AGENTS, LHRH	leuprolide
PITUITARY SUPPRESSIVE AGENTS, LHRH	SUPPRELIN LA KIT (histrelin)