

## Pharmacy and Biopharmacy Policies

Effective September 16, 2020



Policy	Applicable Products	New Policy Overview or Updated Policy Revisions
<b>Acclidinium/Formoterol (Duaklir Pressair) (CP.PCH.23)</b>	Ambetter	Updates include: <ul style="list-style-type: none"> <li>Added Striverdi Respimat a preferred LABA option per core Ambetter formularies</li> <li>Removed Advair HFA as a preferred ICS/LABA option as it is not used for COPD (asthma only)</li> </ul>
<b>Afamelanotide (Scenesse) (CP.PHAR.444)</b>	Ambetter	Updates include: <ul style="list-style-type: none"> <li>Finalize Ambetter line of business</li> </ul>
<b>Blinatumomab (Blinicyto) (CP.PHAR.312)</b>	Medicaid (STAR, STAR Health, STAR Kids, STAR+PLUS), CHIP, and Ambetter	Updates include: <ul style="list-style-type: none"> <li>Ambetter line of business added</li> <li>References reviewed and updated</li> </ul>
<b>Brexpiprazole (Rexulti) (CP.PMN.68)</b>	Ambetter	Updates include: <ul style="list-style-type: none"> <li>Allowed members 65 years old or older to bypass redirections to TCA for major depressive disorder</li> </ul>
<b>Burosumab-twza (Crysvita) (CP.PHAR.11)</b>	Ambetter	Updates include: <ul style="list-style-type: none"> <li>Clarified weight-based dosing limits in initial and continued approval criteria</li> <li>References reviewed and updated</li> </ul>
<b>Cinacalcet (Sensipar) (CP.PHAR.61)</b>	Ambetter	Updates include: <ul style="list-style-type: none"> <li>References reviewed and updated</li> </ul>
<b>Corticosteroid Intravitreal Implants (Iluvien, Ozurdex, Retisert, Yutiq) (CP.PHAR.385)</b>	Medicaid (STAR, STAR Health, STAR Kids, STAR+PLUS), CHIP, and Ambetter	Updates include: <ul style="list-style-type: none"> <li>Added Ambetter line of business, removed Ambetter-Medical Benefit</li> <li>References reviewed and updated</li> </ul>
<b>Daratumumab, Daratumumab-Hyaluronidase-fihj (Darzalex, Darzalex Faspro) (CP.PHAR.310)</b>	Medicaid (STAR, STAR Health, STAR Kids, STAR+PLUS), CHIP, and Ambetter	Updates include: <ul style="list-style-type: none"> <li>Darzalex Faspro added</li> <li>References reviewed and updated</li> </ul>
<b>Deferoxamine (Desferal) (CP.PHAR.146)</b>	Medicaid (STAR, STAR Health, STAR Kids, STAR+PLUS), CHIP, and Ambetter	Updates include: <ul style="list-style-type: none"> <li>Revised Ambetter-medical benefit to Ambetter line of business</li> <li>References reviewed and updated</li> </ul>
<b>Dichlorphenamide (Keveyis) (CP.PCH.04)</b>	Ambetter	Updates include: <ul style="list-style-type: none"> <li>Updated contraindications</li> <li>References reviewed and updated</li> </ul>
<b>Elexacaftor-ivacaftor-tezacaftor (Trikafta) (CP.PHAR.440)</b>	Ambetter	Updates include: <ul style="list-style-type: none"> <li>Revised initial approval criteria: revised the requirement for evidence of clinical severity as defined by an average sweat chloride from &gt; 86 mmol/L to &gt; 60 mmol/L</li> </ul>

		<ul style="list-style-type: none"> <li>Removed in vitro testing requirement demonstrating a baseline chloride transport &lt; 10% of wild type CFTR</li> <li>Removed requirement for lack of responsiveness to other CFTR modulators</li> <li>Removed for members currently using another CFTR modulator switching to Trikafta to show increase in chloride transport of &lt; 10% over baseline</li> <li>Removed positive response requirement after at least 12 weeks of therapy to show chloride transport <math>\geq</math> 10% since baseline requirement</li> <li>Revised Appendix D</li> </ul>
<b>Entrectinib (Rozlytrek) (CP.PHAR.441)</b>	Ambetter	Updates include: <ul style="list-style-type: none"> <li>Finalize Ambetter line of business</li> </ul>
<b>Erdafitinib (Balversa) (CP.PHAR.423)</b>	Ambetter	Updates include: <ul style="list-style-type: none"> <li>Recurrent disease and checkpoint inhibitor prior therapy option added per NCCN</li> <li>References reviewed and updated</li> </ul>
<b>Erlotinib (Tarceva) (CP.PHAR.74)</b>	Ambetter	Updates include: <ul style="list-style-type: none"> <li>added NCCN-supported combination of Tarceva with either Cyramza or bevacizumab</li> <li>References reviewed and updated</li> </ul>
<b>Everolimus (Afinitor, Afinitor Disperz, Zortress) (CP.PHAR.63)</b>	Ambetter	Updates include: <ul style="list-style-type: none"> <li>Added Appendix D with information regarding off-label use of Zortress in heart transplant</li> <li>Updated Appendix C to clarify Zortress's boxed warning in heart transplant</li> </ul>
<b>Fulvestrant (Faslodex Injection) (CP.PHAR.424)</b>	Medicaid (STAR, STAR Health, STAR Kids, STAR+PLUS), CHIP, and Ambetter	Updates include: <ul style="list-style-type: none"> <li>For endometrial carcinoma, added option for use in stage II disease, in combination with sequential external beam radiation therapy</li> <li>References reviewed and updated</li> </ul>
<b>Givosiran (Givlaari) (CP.PHAR.457)</b>	Medicaid (STAR, STAR Health, STAR Kids, STAR+PLUS), CHIP, and Ambetter	Updates include: <ul style="list-style-type: none"> <li>Corrected-for-creatinine requirement removed from diagnostic porphyrin precursor (ALA/PBG) testing criteria to reflect lab reporting variability</li> <li>Examples of ALA/PBG values, uncorrected for creatinine, are added to Appendix E</li> <li>References reviewed and updated</li> </ul>
<b>Glecaprevir/Pibrentasvir (Mavyret) (HIM.PA.SP36)</b>	Ambetter	Updates include: <ul style="list-style-type: none"> <li>CP.PCH.18 retired and HIM.PA.SP36 unretired</li> <li>No significant changes</li> <li>References reviewed and updated</li> </ul>
<b>GLP-1 receptor agonists (CP.PMN.183)</b>	Medicaid (STAR, STAR Health, STAR Kids, STAR+PLUS), CHIP	Updates include: <ul style="list-style-type: none"> <li>Updated "FDA Approved Indications" section to include Trulicity's new FDA indication: cardiovascular risk reduction in patients with established cardiovascular disease or with multiple cardiovascular risk factors</li> <li>Modified criteria to allow Trulicity or Ozempic in patients with established cardiovascular disease or multiple cardiovascular risk factors if contraindicated to the preferred agent Victoza</li> <li>Added new exenatide contraindication to Appendix C</li> <li>References reviewed and updated</li> </ul>
<b>Ipilimumab (Yervoy) (CP.PHAR.319)</b>	Medicaid (STAR, STAR Health, STAR Kids,	Updates include: <ul style="list-style-type: none"> <li>Added FDA-labeled indications of HCC and NSCLC in combination with Opdivo</li> </ul>

	STAR+PLUS), CHIP, and Ambetter	<ul style="list-style-type: none"> <li>References reviewed and updated</li> </ul>
<b>Ixazomib (Ninlaro) (CP.PHAR.302)</b>	Ambetter	Updates include: <ul style="list-style-type: none"> <li>NCCN recommended uses for MM and Waldenstrom added</li> <li>References reviewed and updated</li> </ul>
<b>Leuprolide Acetate (Lupron, Lupron Depot, Eligard, Lupaneta Pack, Fensolvi) (CP.PHAR.173)</b>	Medicaid (STAR, STAR Health, STAR Kids, STAR+PLUS), CHIP, and Ambetter	Updates include: <ul style="list-style-type: none"> <li>revised Ambetter-Medical Benefit to Ambetter line of business</li> <li>Added Fensolvi (new dosage form) to the policy for Central Precocious Puberty</li> <li>Added off-label NCCN indication and criteria for salivary gland tumor</li> <li>References reviewed and updated</li> </ul>
<b>Lidocaine transdermal (Lidoderm, ZTIido) (CP.PMN.08)</b>	Ambetter	Updates include: <ul style="list-style-type: none"> <li>Removed all mention of redirecting to HIM.PA.103 for ZTIido</li> <li>References reviewed and updated</li> </ul>
<b>Luspatercept-aamt (Reblozyl) (CP.PHAR.450)</b>	Medicaid (STAR, STAR Health, STAR Kids, STAR+PLUS), CHIP, and Ambetter	Updates include: <ul style="list-style-type: none"> <li>Criteria added for new FDA indication MDS</li> <li>References reviewed and updated</li> </ul>
<b>Neratinib (Nerlynx) (CP.PHAR.365)</b>	Ambetter	Updates include: <ul style="list-style-type: none"> <li>Added NCCN Compendium supported use in combination with capecitabine for CNS metastases</li> <li>References reviewed and updated</li> </ul>
<b>Netupitant and Palonosetron (Akynzeo), Fosnetupitant and Palonosetron (Akynzeo IV) (CP.PMN.158)</b>	Medicaid (STAR, STAR Health, STAR Kids, STAR+PLUS), CHIP, and Ambetter	Updates include: <ul style="list-style-type: none"> <li>New IV dosage formulation added</li> </ul>
<b>Nintedanib (Ofev) (CP.PHAR.285)</b>	Ambetter	Updates include: <ul style="list-style-type: none"> <li>Criteria added for new FDA indication: chronic fibrosing ILD with a progressive phenotype</li> <li>References reviewed and updated</li> </ul>
<b>Nivolumab (Opdivo) (CP.PHAR.121)</b>	Medicaid (STAR, STAR Health, STAR Kids, STAR+PLUS), CHIP, and Ambetter	Updates include: <ul style="list-style-type: none"> <li>Updated HCC criteria to include no previous treatment with a checkpoint inhibitor based on NCCN recommendation</li> <li>Added criteria for FDA-labeled indications of NSCLC &amp; ESCC</li> <li>Updated SCLC indication for optional use in combination with ipilimumab per updated NCCN compendium</li> <li>Added NCCN compendium-supported indications of small bowel adenocarcinoma and T-cell lymphoma</li> </ul>
<b>Obeticholic Acid (Ocaliva) (CP.PHAR.287)</b>	Ambetter	Updates include: <ul style="list-style-type: none"> <li>Added preemptive criteria for the pending FDA approval of NASH indication</li> </ul>
<b>Octreotide Acetate (Sandostatin, Sandostatin LAR Depot, Bynfezia, Mycapssa) (CP.PHAR.40)</b>	Medicaid (STAR, STAR Health, STAR Kids, STAR+PLUS), CHIP, and Ambetter	Updates include: <ul style="list-style-type: none"> <li>Added Mycapssa to policy</li> </ul>

<b>Olaparib (Lynparza) (CP.PHAR.360)</b>	Ambetter	<p>Updates include:</p> <ul style="list-style-type: none"> <li>Criteria added for two newly FDA-approved indications: 1) HRD-positive ovarian cancers in combination with bevacizumab after bevacizumab primary therapy, and 2) HRR-mutated mCRPC.</li> </ul>
<b>Palbociclib (Ibrance) (CP.PHAR.125)</b>	Ambetter	<p>Updates include:</p> <ul style="list-style-type: none"> <li>Added tablet formulation</li> </ul>
<b>Palivizumab (Synagis) (CP.PHAR.16)</b>	Ambetter	<p>Updates include:</p> <ul style="list-style-type: none"> <li>Seasonal coverage criteria are added to all indications</li> </ul> <p>Related AAP/CDC guidance is added to Appendix D</p>
<b>Paricalcitol Injection (Zemlar) (CP.PHAR.270)</b>	Medicaid (STAR, STAR Health, STAR Kids, STAR+PLUS), CHIP, and Ambetter	<p>Updates include:</p> <ul style="list-style-type: none"> <li>Revised Ambetter-medical benefit to Ambetter line of business</li> <li>References reviewed and updated</li> </ul>
<b>Pembrolizumab (Keytruda) (CP.PHAR.322)</b>	Medicaid (STAR, STAR Health, STAR Kids, STAR+PLUS), CHIP, and Ambetter	<p>Updates include:</p> <ul style="list-style-type: none"> <li>New FDA approved dosing of 400 mg every 6 weeks added to all labeled adult indications</li> <li>NSCLC: first-line removed from combination with chemotherapy per NCCN</li> <li>Brain metastasis moved under PD-L1 positive disease per NCCN</li> <li>SCLC: relapsed disease added per NCCN</li> <li>cHL: Keytruda as single-agent therapy added per NCCN</li> <li>HNSCC: first-line therapy requirement removed from combination platinum/FU therapy per NCCN</li> <li>MSI-H/dMMR tumors: first-line therapy for occult primary tumor and small bowel added per NCCN</li> <li>HCC: Child-Pugh Class A added per NCCN/pivotal trial with no prior checkpoint inhibitor therapy caveat per NCCN</li> <li>Three new FDA approved indications added: 1) MSI-H/dMMR CRC first-line (adults), 2) TMB-H (adults/pediatrics), 3) cSCC (adults); NCCN off-label Keytruda use as first-line for MSI-H tumors is limited to adults</li> <li>NCCN off-label criteria set is limited to adults; endometrial carcinoma criteria set is limited to 24 months of therapy; MSI-H/TMB-H CNS tumors excluded for pediatrics per PI; indication table added with directives to MSI-H/TMB-H criteria sets for appropriate cancers; BCG Appendix D added; TMB-H solid tumor examples added to Appendix E; references reviewed and updated</li> </ul>
<b>Pomalidomide (Pomalyst) (CP.PHAR.116)</b>	Ambetter	<p>Updates include:</p> <ul style="list-style-type: none"> <li>Criteria revised for newly FDA approved indication of KS</li> <li>Allowed use in non-AIDS-related disease</li> <li>Added immunologist as a prescriber option per specialist feedback</li> <li>For AIDS-related disease: added requirement that Pomalyst must be prescribed in combination with HAART and modified requirement from failure of 2 agents to specify first line doxorubicin and paclitaxel per NCCN and European consensus guidelines</li> </ul>

		<ul style="list-style-type: none"> <li>Modified max daily dose from 4 mg/day to 5 mg/day per FDA labeling</li> </ul>
<b>Quetiapine ER (Seroquel XR) (CP.PMN.64)</b>	Ambetter	Updates include: <ul style="list-style-type: none"> <li>Allowed members 65 years old or older to bypass redirections to TCA for major depressive disorder</li> </ul>
<b>Ramucirumab (Cyramza) (CP.PHAR.119)</b>	Medicaid (STAR, STAR Health, STAR Kids, STAR+PLUS), CHIP, and Ambetter	Updates include: <ul style="list-style-type: none"> <li>Added criteria for new FDA indication of NSCLC in combination with Tarceva</li> <li>revised Ambetter-medical benefit to Ambetter line of business</li> <li>References reviewed and updated.</li> </ul>
<b>Rucaparib (Rubraca) (CP.PHAR.350)</b>	Ambetter	Updates include: <ul style="list-style-type: none"> <li>Criteria added for new FDA indication: metastatic CRPC</li> <li>For both indications, added requirement against prior use of a PARP inhibitor</li> <li>Added Appendix D</li> <li>References reviewed and updated.</li> </ul>
<b>Sargramostim (Leukine) (CP.PHAR.295)</b>	Medicaid (STAR, STAR Health, STAR Kids, STAR+PLUS), CHIP, and Ambetter	Updates include: <ul style="list-style-type: none"> <li>For ARS indication added weight based dosing to criteria set</li> <li>References reviewed and updated</li> </ul>
<b>Selinexor (Xpovio) (CP.PHAR.431)</b>	Ambetter	Updates include: <ul style="list-style-type: none"> <li>Criteria added for new FDA-approved indication: DLBCL</li> <li>References reviewed and updated</li> </ul>
<b>SGLT2 inhibitors (HIM.PA.91)</b>	Ambetter	Updates include: <ul style="list-style-type: none"> <li>Criteria added for Farxiga's new FDA indication: heart failure with reduced ejection fraction</li> </ul>
<b>Sofosbuvir/Velpatasvir (Epclusa) (HIM.PA.SP1)</b>	Ambetter	Updates include: <ul style="list-style-type: none"> <li>CP.PCH.21 retired; HIM.PA.SP1 unretired</li> <li>No clinically significant changes</li> <li>References reviewed and updated</li> <li>Added updated FDA-labeled dosing for post-liver transplant setting</li> </ul>
<b>Sofosbuvir/Velpatasvir/Voxilaprevir (Vosevi) (HIM.PA.SP63)</b>	Ambetter	Policy includes: <ul style="list-style-type: none"> <li>Policy created (adapted from CP.PCH.22 which is being retired)</li> </ul>
<b>Tadalafil BPH - ED (Cialis) (CP.PMN.132)</b>	Ambetter	Updates include: <ul style="list-style-type: none"> <li>For ED criteria set removed criteria requiring request for formulary product as criteria would also apply for non-formulary requests</li> </ul> References reviewed
<b>Tazemetostat (Tazverik) (CP.PHAR.452)</b>	Ambetter	Updates include: <ul style="list-style-type: none"> <li>Added criteria set for two new FDA approved FL indications</li> <li>References reviewed and updated</li> </ul>
<b>Teprotumumab (Tepezza) (CP.PHAR.465)</b>	Medicaid (STAR, STAR Health, STAR Kids, STAR+PLUS), CHIP, and Ambetter	Updates include: <ul style="list-style-type: none"> <li>Added requirement that member has not had previous surgical intervention for TED consistent with clinical trial exclusion criteria</li> </ul>
<b>Tesamorelin (Egrifta SV) (CP.PHAR.109)</b>	Ambetter	Updates include: <ul style="list-style-type: none"> <li>Replaced old formulation Egrifta with new formulation Egrifta SV</li> <li>References reviewed and updated</li> </ul>

<b>Tolvaptan (Jynarque, Samsca) (CP.PHAR.27)</b>	Ambetter	<p>Updates include:</p> <ul style="list-style-type: none"> <li>• Updated product availability</li> <li>• Updated Jynarque boxed warnings as per updated prescribing information</li> <li>• References reviewed and update</li> </ul>
<b>Topical Acne Treatment (HIM.PA.71)</b>	Ambetter	<p>Updates include:</p> <ul style="list-style-type: none"> <li>• Added Amzeeq to criteria with age requirement 9 years or older per prescribing information</li> </ul>
<b>Trifarotene (Aklief) (CP.PMN.225)</b>	Ambetter	<p>Updates include:</p> <ul style="list-style-type: none"> <li>• Finalize Ambetter line of business</li> </ul>
<b>Ubrogepant (Ubrelevy) (CP.PHAR.476)</b>	Ambetter	<p>Updates include:</p> <ul style="list-style-type: none"> <li>• Revised requirement 'for monthly quantities &gt; 1 box of 6 tablets per month' to 10 tablets per month as this is the smallest available package size</li> <li>• Updated Section VI to remove the 6 and 8 tablet package sizes</li> </ul>
<b>Umeclidinium/Vilanterol (Anoro Ellipta) (HIM.PA.106)</b>	Ambetter	<p>Updates include:</p> <ul style="list-style-type: none"> <li>• Added Arcapta Neohaler and Striverdi Respimat as preferred LABAs and specified that generic (as opposed to brand) Advair Diskus and Symbicort are preferred per core Ambetter formulary status</li> <li>• Updated Appendix C to reflect revised CI language</li> </ul> <p>References reviewed and updated</p>
<b>Vigabatrin (Sabril) (CP.PHAR.169)</b>	Ambetter	<p>Updates include:</p> <ul style="list-style-type: none"> <li>• References reviewed and updated</li> </ul>
<b>Vorinostat (Zolinza) (CP.PHAR.83)</b>	Ambetter	<p>Updates include:</p> <ul style="list-style-type: none"> <li>• Appendix D subtype classification updated per NCCN/WHO-EORTC 2018</li> <li>• References reviewed and updated</li> </ul>
<b>Vortioxetine (Trintellix) (CP.PMN.65)</b>	Ambetter	<p>Updates include:</p> <ul style="list-style-type: none"> <li>• Added contraindications and boxed warnings</li> <li>• References reviewed and updated</li> </ul>