Summary of Updates
PHC P & T Committee, October 5, 2023
Effective Date: January 1, 2024

The following TAR criteria, coverage requirements, &/or restrictions, apply to PHC's Medical Drug Benefit (also referred to as Physician Administered Drugs). These are drugs that are (1) purchased by a medical office, clinic or hospital, (2) administered to the member in a medical setting (not for use at home), and (3) billed directly to PHC as a medical claim using HCPCS codes (and NDCs where appropriate). For pharmacy drug coverage, please refer to Medi-Cal Rx documents on the State's Medi-Cal Rx web pages.

NOTE: Brand names are for reference only. Criteria and billing requirements apply to the drug itself (active ingredient) regardless of the manufacturer/brand, unless otherwise specified.

***Effective Date for all changes below**: January 1st, 2024, unless otherwise specified.*

Class Review: Anti-Infective Agents		
HCPCS	**HCPCS Description**	**Summary of Updates**
J3090	Injection, tedizolid phosphate, 1 mg (Sivextro™)	• Minor revisions to criteria wordings. • Update age limits to match FDA-approved labeling. • Added case-by-case reference
J2407	Injection, oritavancin (orbactiv), 10 mg (Orbactiv™)	
J0875	Injection, dalbavancin, 5 mg (Dalvance™)	
J3490	Unclassified drugs: Posaconazole 300 mg/16.7 ml single dose vial (Noxafil™)	• Minor revisions to criteria wordings. • Update FDA-approved indications and approved ages • Remove exclusion criteria • Addition of case-by-case reference for off label use.
J0349	Injection, rezafungin 200mg vial (Rezzayo™)	• Rezafungin requests to be reviewed per PHC criteria document, *Standard Requirement for Antifungal Agents,* case-by-case review.
J0878	Injection, daptomycin, 1 mg (Cubicin™)	• Minor reformatting • Added FDA approved ages to age limit • Added standard off-label use reference
J0877	Injection, daptomycin (hospira), not therapeutically equivalent to J0878, 1 mg	

Class Review: Antineoplastic & Adjunctive Agents		
HCPCS	**HCPCS Description**	**Summary of Updates**
J9041	Injection, Bortezomib, 0.1 mg (Velcade™ & generic equivalents)	• Add TAR requirement

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J9046	Injection, Bortezomib, (Dr. Reddy's), not therapeutically equivalent to J9041, 0.1 mg	• J9041, J9049, J9051: Addition of 3 off-label diagnosis for claims allowed without a TAR, as recommended by NCCN. • J9046 (Dr. Reddy's) and J9048 (Fresenius Kabi) to have a TAR requirement as of 1/1/24.
J9048	Injection, Bortezomib, (Fresenius Kabi), not therapeutically equivalent to J9041, 0.1 mg	
J9049	Injection, Bortezomib, (Hospira), not therapeutically equivalent to J9041, 0.1 mg	
J9051	Injection, Bortezomib, (Maia/Fosun), not therapeutically equivalent to J9041, 0.1 mg	
Q2041	Axicabtagene ciloleucel, up to 200 million autologous anti-cd19 car positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose (Yescarta™)	• New CAR-T criteria document has been established which consolidates all CAR-T brands into a single document for ease in keeping requirements up to date. The requirements themselves remain largely unchanched, with the following minor wording changes made: ○ Yescarta™: Added relapsed or refractory follicular lymphoma as a covered use and what documentation is required for this indication ○ Tecartus™: Added relapsed or refractory B-cell precursor ALL as a covered use and what documentation is required for this indication ○ Kymriah™: Added relapsed or refractory follicular lymphoma as a covered use and what documentation is required for this indication ○ Added wording showing that requires will be reviewed by a relevant specialist by way of PHC's External Independent Medical Review policy
Q2053	Brexucabtagene autoleucel, up to 200 million autologous anti-cd19 car positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose (Tecartus™)	
Q2042	Tisangenlecleucel, up to 600 million car-positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose (Kymriah™)	
J1952	Leuprolide Injectable, Camcevi, 1 mg	• New criteria: Requirements for Leuprolide mesylate (Camcevi™)

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Class Review: Hematological Agents		
HCPCS	**HCPCS Description**	**Summary of Updates**
J1303	Injection, ravulizumab-cwvz, 10 mg (Ultomiris™)	• Update criteria for age limit per package labeling • Add dosing for PNH <18yo • Correct exclusion criteria to replace drug Ultomiris™ to Soliri™
J1300	Injection, eculizumab, 10 mg (Soliris™)	• Update drug specific criteria to edit covered use to reflect FDA package labeling which no longer says refractory gMG
J2506	Injection, pegfilgrastim, excludes biosimilar, 0.5 mg (Neulasta, Neulasta Onpro™)	• Add drug Nyvepria™and Flynetra™ to the biosimilar list as preferred biosimilar products
Q5127	Injection, pegfilgrastim-fpgk, biosimilar, 0.5 mg (Stimufend™)	• New criteria to mirror Neulasta™ criteria to require use of other preferred biosimilars.
J1449	Injection, eflapegrastim-xnst, 0.1 mg (Rolvedon™)	• New drug specific criteria to mirror Neulasta™ criteria for the indication of prevention of chemotherapy-induced neutropenia with trial and failure of a pegfilgrastim product and age limit of 18 years and older.
J1442	Injection, filgrastim (g-csf), excludes biosimilars, 1 microgram (Neupogen™)	• Add Relueko™ to biosimilar list for the options that must be tried and failed
Q5110	Injection, , filgrastim-aafi, biosimilar, (nivestym), 1 microgram (Nivestym™)	• Add ICD-10s for stem cell donation.
J1447	Injection, tbo-filgrastim, 1 microgram (Granix™)	• Remove age limit
J0791	Injection, crizanlizumab-tmca, 5 mg (Adakveo™)	• Update drug specific criteria to remove Oxbryta™ from the trial and failure requirements and replace with Endari™.
J0896	Injection, luspatercept-aamt, 0.25 mg (Reblozyl™)	• Add age limit of 18 years and older per package labeling. • Edit off-label use reference

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J2796	Injection, romiplostim, 10 micrograms (Nplate™)	• Update drug specific criteria to add new FDA approved indications • Add Doptelet™ as an option with Promacta™ • Remove exclusion wordings to align with updated FDA indications.
J3590	Unclassified Biologic (valoctocogene roxaparvovec-rvox) (Roctavian™)	• New drug specific criteria: Requirements for Valoctocogene roxaparvovec-rvox (Roctavian™)

Class Review: Psychotherapeutic And Neurological Agents - Miscellaneous

HCPCS	HCPCS Description	Summary of Updates
J2350	Ocrelizumab (Ocrevus™)	• Update drug specific criteria for the addition of contraindication with active HBV infection • Add requirement for consultation with liver specialist for members • While criteria is newly associated with Briumvi, it shares the same criteria as Ocrevus. A new criteria document was created to have single consolidated document for for both Briumvi™ and Ocrevis™
J2329	ublituximab-xiiy (Briumvi™)	

Miscellaneous Changes Falling Outside of Scheduled Drug Class Reviews

HCPCS	HCPCS Description	Summary of Updates
90378	Respiratory syncytial virus, monoclonal antibody, recombinant, for intramuscular use, 50 mg, each (Synagis™)	• Add Beyfortus as new option for prevention of RSV in children as being the preferred agent. • Update criteria to remove obsolete pharmacy benefit wording.

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New CMS & DHCS HCPCS Codes, Effective 10/1/2023		
HCPCS	**HCPCS Code & Drug Descriptions**	**Coverage Status**
Antineoplastic & Adjunctive Agents		
C9155	Injection, epocoritamabbysp, 0.16 mg (Epkinly™)	TAR required
J9051	Injection, bortezomib (maia), not therapeutically equivalent to J9041, 0.1 mg	·Diagnosis restriction: mantel cell lymphoma and multiple myeloma, Peripheral T-cell lymphoma, Systemic light chain amyloidosis, Waldenstrom Macroglobulinemia/ Lymphoblastic Lymphoma ·Specialty: Non-hospital facility providers limited to oncologists & hematologists. ·Dose limit: 35 units (3.5 mg) per day. ·Minimum Age: 18 years
J9064	Injection, cabazitaxel (sandoz), not therapeutically equivalent to J9043, 1mg	TAR required
J9345	Injection, retifanlimabdlwr,1 mg (Zynyz™)	TAR required
Anti-infectives - Antibiotic		
J0874	Injection, daptomycin (baxter), not therapeutically equivalent to J0878, 1mg (solution)	TAR required
Anti-infectives - Antifungal		
J0349	Injection, rezafungin, 1mg (Rezzayo™)	TAR required
Dermatologic Agents		
J7353	Anacaulase-bcdb, 8.8% gel, 1 gram (Nexobrid™)	TAR required
Endocrine & Metabolic Agents		
J0801	Injection, corticotropin (acthar gel), up to 40 units	TAR required
J0802	Injection, corticotropin (ani), up to 40 units	TAR required
Gastrointestinal Agents		
C9153	Injection, amisulpride, 1mg (Barhemsys™)	TAR required
Hematologic Agents		

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J0889	Daprodustat, oral, 1 mg, (for esrd on dialysis) (Jesduvroq™)	• Minimum age: 18 years • Member on dialysis ≥ 4 months • Not to exceed 24 units (24 mg) per day.
Immunosuppressives		
J7519	Injection, mycophenolate mofetil, 10 mg (Cellcept IV ™)	• Requires organ transplant indication (kidney, liver, heart, lung, heart-lung). • Dose limit of 200 units (2,000 mg) per day based on max adult dose of 1,000 mg Q12 hrs.
Neuromuscular Agents		
C9157	Injection, tofersen, 1 mg (Qalsody™)	TAR Required
Ophthalmologic Agents		
J2781	Injection, pegcetacoplan, intravitreal, 1 mg (Syfovre™)	TAR Required

Additions and Changes to J3490/Z7610 Unclassified NDC Coverage ***Brand names are listed for reference only; coverage information also applies to generics.***	
Generic (Brand)	**Coverage Requirements/Limits**
Analgesics	
Ibuprofen OTC 200 mg tablets & capsules	Addition, no restriction
Ibuprofen OTC 100 mg chewable tablets	Addition, no restriction
Morphine Sulfate 60 mg, 100 mg tablets (MS Contin™)	Limited to hospital & ambulatory surgery center locations, with a maximum of 10 tablets dispensed on a single date of service.
Celecoxib capsules (Celebrex™) 50, 100 mg, 200 mg, 400 mg	Remove limit of 1 per day
Cardiovascular Agents	
Nebivilol (Bystolic™) 2.5, 5, 10, 20 mg tablets	Addition, no restriction
Central Nervous System Agents (Anxiolytics, Antidepressants, Sedatives, Hypnotics)	

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Zolpidem IR 5 mg, 10 mg (Ambien™)	Remove limit of 1/day
Zolpidem ER 6.25 mg, 12.5 mg (Ambien CR™)	Remove limit of 1/day
Dermatologic Agents	
Lidocaine 2% topical gel, OTC (Regenecare™, Regenecare HA™)	Limited to ED locations only for 1 tube
Electrolyte Regulation Agents	
Urea 15 g powder packets for oral solution (Ure-NA™)	Addition, no restriction
Endocrine & Metabolic	
Empagliflozin 10, 25 mg tablets (Jardiance™)	Addition, no restriction
Linagliptin 5 mg tablets (Tradjenta™)	Addition, no restriction
Genitourinary	
Trospium Chloride 20 mg tablets,	Remove limit of 2/day
Trospium Chloride 60 mg ER capsules (Sanctura™)	Remove limit of 1/day
Neuromuscular	
Lacosamide 10 mg/1 ml oral solution (Vimpat™) in 5, 10, 15, and 20 ml unit dose cups; 200 & 465 ml multi-dose bottles	Addition, no restriction other than must bill as 1 unit=1 unit dose oral syringe, do not use # of ML as the unit count. Multi-dose 200 &465 ml bottle should be billed as count of 1 for each bottle used and remarks to indicate actual # of ML administered (will be reimbursed by the # of ML used).
Clobazam 10, 20 mg tablets (Onfi™)	Remove limit of 1 per day
Nutritional Agents	
Vitamin C 250 mg, 500 mg, 1,000 mg tablets	Addition, no restriction
Multivitamins for adults:	Adult strength tablets and chewable: Addition, no restriction

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• Tablets • Chewable tablets • Oral liquid (Centrum™) in 236 ml multi-dose and 15 ml single dose	Adult oral liquid: Addition, no restriction other than must bill actual # of ML administered (will be reimbursed by the # of ML used) rather than the default of per bottle
Psychotherapeutic & Neurological, Misc	
Memantine 5 mg, 10 mg tablets (Namenda™)	Remove limit of 2/day