Summary of Updates
PHC P & T Committee, April 6, 2023
Effective Date: July 1, 2023

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**: July 1st, 2023, unless otherwise specified.*

Class Review: Antihistamine, Nasal, Cough and Cold, Resp, Misc. Agents			
HCPCS	**HCPCS Description**	**How Supplied**	**Summary of Updates**
J3590	Injection, dupilumab, per 1 pen or prefilled syringe	Dupixent™ for subcutaneous (SC) injection: – Prefilled Syringe: 100 mg/0.67 ml, 200 mg/1.14 ml & 300 mg/2 ml – Pen: 200 mg/1.14 ml & 300 mg/2 ml	• Criteria document now archived because this drug is primarily supplied by pharmacies through Medi-Cal Rx. • PHC will use the criteria document, "Standard Requirements for Self-Administered Drug", in the event a medical provider submits a TAR.
J2182	Injection, mepolizumab, per 1 mg	Nucala™ for SC injection: – Autoinjector Pen: 100 mg/ml – Prefilled Syringe: 40 mg/ 0.4 ml, & 100 mg/ml – Vial: 100 mg	• Updated requirements for the treatment of asthma and eosinophilic granulomatosis w/polyangiitis • Added requirements based on dosage form: distinguishing between the products that may be self-administered and products that must be administered by a healthcare provider.
J0517	Injection, benralizumab, per 1 mg	Fasenra™ for subcutaneous (SC) injection: – Autoinjector pen:30 mg/ 1 ml – Prefilled Syringe: 30 mg/1 ml	• Updated exclusion criteria. • Updated requirements for the treatment of asthma • Added requirements based on dosage form: distinguishing between the products that may be self-administered and products that must be administered by a healthcare provider.

Class Review: Antihistamine, Nasal, Cough and Cold, Resp, Misc. Agents continued			
HCPCS	**HCPCS Description**	**How Supplied**	**Summary of Updates**
J2356	Injection, tezepelumab, per 1 mg	Tezspire™ for subcutaneous (SC) injection: – Autoinjector pen: 210 mg/ 1.91 ml – Prefilled Syringe: 210 mg/ 1.91 ml	• Updated exclusion criteria. • Added immunologist to the allowed specialist prescribers • Updated requirements for the treatment of asthma • Added requirements based on dosage form: distinguishing between the products that may be self-administered and products that must be administered by a healthcare provider.
J2357	Injection, omalizumab, per 5 mg	Xolair™ for subcutaneous (SC) injection: – Prefilled Syringe: 75 mg/ 0.5 ml, & 150 mg/1 ml – Vial: 150 mg	• Enhanced wording for covered uses • Updated Exclusion criteria. • Updated requirement wording for the treatment of asthma and chronic idiopathic urticaria • Removed provider restrictions. • Added requirements based on dosage form: distinguishing between the products that may be self-administered and products that must be administered by a healthcare provider.
Class Review: Antineoplastic Agents & Adjunctive Therapies			
HCPCS	**HCPCS Description**	**How Supplied**	**Summary of Updates**
J9271	Injection, pembrolizumab, per 1 mg	Keytruda™ for intravenous (IV) injection: – Vial: 100 mg/4 ml	• Criteria document now archived due to rapidly changing indications and treatment guidelines • TARs will be reviewed on a case-by-case basis using PHC's "General Requirements for Antineoplastic Agents", along with NCCN guidelines and other standards of care reported in compendia.

Class Review: Vaccines, Toxoids, Immunizations, Allergenic Extracts, Misc.			
HCPCS	**HCPCS Description**	**How Supplied**	**Summary of Updates**
J1551	Immune Globulin, per 100 mg	Cutaquig™ for subcutaneous (SC) injection: – Vial: 1 g/6 ml, 1.65 g/10 ml, 2 g/12 ml, 3.3 g/20 ml, 4 g/24 ml, & 8 g/48 ml	• Updated wording for : ○ Covered uses ○ Existing criteria ○ Age restriction • New criteria for updated covered uses that did not previously have criteria. • New renewal criteria for CDIP, hypogammaglobulinemia, prophylaxis, & MMN (no change to ITP or Guillain-Barre)
J1555	Immune Globulin, per 100 mg	Cuvitru™ 20% for subcutaneous (SC) injection: – Vial: 1 g/5 ml, 2 g/10 ml, 4 g/20 ml, 8 g/40 ml, & 10 g/50 ml	
J1559	Immune Globulin, per 100 mg	Hizentra™, 20% for subcutaneous (SC) injection: – Prefilled syringe: 1 g/5 ml, 2 g/10 ml, & 4 g/20 ml – Vial: 1g/5 ml, 2 g/10 ml, 4 g/20 ml, & 10 g/50 ml	
J1575	Immune Globulin, per 500 mg	Hyqvia™ for subcutaneous (SC) injection: – Kit: 2.5 g IG/25 ml with 200 u hyaluronidase, 5 g IG/50 ml with 400 u hyaluronidase, 10 g IG/800 u hyaluronidase, 20 g IG/1,600 u hyaluronidase, & 30 g IG/2,400 u hyaluronidase	
J1558	Immune Globulin, per 100 mg	Xembify™ 20%, for subcutaneous (SC) injection: – Vial:1 g/5 ml, 2 g/10 ml, 4 g/20 ml, & 10 g/50 ml	
J1460	Immune Globulin, per 1 ml	Gamastan™ S/D, for intramuscular (IM) injection: – Vial: 15% (150 mg) to 18% (180 mg)/ ml	
J1560	Immune Globulin, (over 10 ml), per 10 ml	Gamastan™ S/D for intramuscular (IM) injection: – Vial: 15% (1,500 mg) to 18% (1,800 mg)/ 10 ml	
J1554	Immune Globulin, per 500 mg	Asceniv™, for intravenous (IV) injection: – Vial: 5 g/50 ml	
J1556	Immune Globulin, per 500 mg	Bivigam™, for intravenous (IV) injection: – Vial: 5 g/50 ml, & 10 g/ 100 ml	

Class Review: Vaccines, Toxoids, Immunizations, Allergenic Extracts, Misc. continued			
HCPCS	**HCPCS Description**	**How Supplied**	**Summary of Updates**
J1572	Immune Globulin, 5%, 10%, per 500 mg	Flebogamma™ DIF for intravenous (IV) injection: – Vial: 0.5 g/10 ml, 2.5 g/50 ml, 5 g/50 ml, 5 g/100 ml, 10 g/100 ml, 10 g/200 ml, 20 g/200 ml, & 20 g/400 ml	• Updated wording for: ○ Covered uses ○ Existing criteria ○ Age restriction • New criteria for updated covered uses that did not previously have criteria. • New renewal criteria for CDIP, hypogammaglobulinemia, prophylaxis, & MMN (no change to ITP or Guillain-Barre)
J1569	Immune Globulin, non-lyophilized, per 500 mg	Gammagard™/non-lyophilized, for intravenous (IV) injection: – Vial: 1 g/10 ml, 2.5 g/25 ml, 5 g/50 ml, 10 g/100 ml, 20 g/200 ml, & 30 g/300ml	
J1566	Immune Globulin, less IgA/ this is lyophilized, per 500 mg	Gammagard™ S/D for intravenous (IV) injection: – Vial: 5g, & 10 g	
J1561	Immune Globulin, G per 500 mg	Gammaked™, for intravenous (IV) injection: – Vial: 1 g/10 ml, 5 g/50 ml, 10 g/100 ml, & 20 g/200 ml	
J1557	Immune Globulin, 5%, 10%, per 500 mg	Gammaplex™ for intravenous (IV) injection: – Vial: 5 g/50 ml, 5 g/100 ml, 10 g/100 ml, 10 g/200 ml, 20 g/200 ml, & 20 g/400 ml	
J1561	Immune Globulin, per 500 mg	Gamunex-C™, for intravenous (IV) injection: – Vial: 1 g/10 ml, 2.5 mg/25 ml, 5 g/50 ml, 10 g/100 ml, 20 g/200 ml, & 40 g/400 ml	
J1568	Immune Globulin, 5%, 10%, per 500 mg	Octagam™ for intravenous (IV) injection: – Vial: 1 g/20 ml, 2 g/20 ml, 2.5 g/50 ml, 5 g/100 ml, 5 g/50 ml, 10 g/100 ml, 10 g/200 ml, 20 g/200 ml, 25 g/500 ml, & 30 g/300 ml	
J1576 *J1599 deactivated as of 6/30/23)*	Immune Globulin - ifas, per 500 mg	Panzyga™, for intravenous (IV) injection: – Vial: 1 g/10 ml, 2.5 g/25 ml, 5 g/50 ml, 10 g/100 ml, 20 g/200 ml, & 30 g/300 ml	
J1459	Immune Globulin, per 500 mg	Privigen™ for intravenous (IV) injection: – Vial: 5 g/50 ml, 10 g/100 ml, 20 g/200 ml, & 40 g/400 ml	

Miscellaneous Changes Falling Outside of Scheduled Drug Class Reviews			
HCPCS	**HCPCS Description**	**How Supplied**	**Summary of Updates**
J1411	Injection, etranacogene dezaparvovec-drlb, per therapeutic dose	Hemgenix™ for intravenous (IV) injection: – Vial: Suspension; 1 x 10^{13} gc/mL (each vial contains no less than 10 ml)	• New criteria created for the treatment of hemophilia B
J3490	Injection, betibeglogene autotemcel, per therapeutic dose	Zynteglo™ for intravenous (IV) injection: – Up to 4 infusion bags each containing: 2.0 to 20 $\times 10^{6}$ cells/mL suspended in cryopreservation solution. Each infusion bag contains approximately 20 mL	• New criteria created for the treatment of beta thalassemia
J3490	Injection, lecanemab-irmb, per therapeutic dose	Leqembi™ for intravenous (IV) injection: – Vial: 200 mg/2 ml, & 500 mg/5 ml	• New criteria created for the treatment of Alzheimer's disease
J0172	Injection, aducanumab-avwa, per 2 mg	Aduhelm™ for intravenous (IV) injection: – Vial: 170 mg/1.7 ml, & 300 mg/3 ml	• Updated wording for: ○ Age restriction ○ Prescriber restriction • Updated requirements for initial treatment requests • Updated requirements for renewal requests

New CMS & DHCS HCPCS Codes, Effective 4/1/2023		
NEW BILLING CODES – 503(b) NDCs		
HCPCS	**HCPCS Code & Drug Descriptions**	**Coverage Status**
Antineoplastic & Adjunctive Agents		
J9196	Injection, gemcitabine HCL (Accord), per 1 mg, not therapeutically equivalent to J9201, 200 mg	No restrictions
J9294	Injection, pemetrexed (Hospira), not therapeutically equivalent to J9305, per 10 mg	Minimum age: 18 yrs Frequency: Once every 21 days
J9296	Injection, pemetrexed (Accord), not therapeutically equivalent to J9305, 10 mg	
J9297	Injection, pemetrexed (Sandoz), not therapeutically equivalent to J9305, per 10 mg	
Other		
J0612	Injection, calcium gluconate (Fresenius Kabi), per 10 mg	No restrictions
NEW BILLING CODES -- NDA, ANDA NDCs		
HCPCS	**HCPCS Code & Drug Descriptions**	**Coverage Status**
Antineoplastic & Adjunctive Agents		
Q5129	Injection, bevacizumab-add (Vegzelma™), biosimilar, per 10 mg	TAR required (Zirabev & Mvasi preferred)

C9146	Injection, mirvetuximab soravtansine-gynx (Elahere™), per 1 mg	TAR required
C9147	Injection, tremelimumab-actl (Imjudo™), per 1 mg	TAR required
C9148	Injection, teclistamab-cqyv (Tecvayli™), per 0.5 mg	TAR required
J0208	Injection, sodium thiosulfate (Pedmark™), per 100 mg	TAR required
J1449	Injection, eflapegrastim-xnst (Roveldon™), per 0.1 mg	TAR required
Q5127	Injection, pegfilgrastim-fpgk (Stimufend™), biosimilar, per 0.5 mg	TAR required
Q5130	Injection, pegfilgrastim-pbbk (Fylnetra™), biosimilar, per 0.5 mg	1) Maximum dose: 6 mg (12 units) per day 2) ICD-10 requirement: • D70.1 - Agranulocytosis due to chemotherapy) OR • Z51.11 - Encounter for antineoplastic chemotherapy
Other		
C9145	Injection, aprepitant (Aponvie™), per 1 mg	TAR required
C9149	Injection, teplizumab-mzwv (Tzield™), per 5 mcg	TAR required
J1411	Injection, etranacogene dezaparvovec-drlb (Hemgenix™), per therapeutic dose	TAR required
Q5128	Injection, ranibizumab-eqrn (Cimerli™), biosimilar, per 0.1 mg	TAR required
J0218	Injection, Olipudase alfa-rpcp (Xenpozyme™), per 1 mg	TAR required
J1747	Injection, spesolimab-sbzo (Spevigo™), per 1 mg	TAR required
J2403	Topical, chloroprocaine HCL (Iheezo™), per 1 mg	TAR required
J0613	Injection, calcium gluconate (WG critical care), per 10 mg	No restrictions

Additions to NDC Covered Drugs (J3490/Z7610 Unclassified NDC Claims) *Brand names are listed for reference only; coverage information also applies to generics.*	
Generic (Brand)	**Coverage Requirements/Limits**
Analgesics	
Acetaminophen/Aspirin/Caffeine 250/250/65 mg tablet (Excedrin™, Excedrin Extra Strength™, Excedrin Migraine™)	No restriction
Acetaminophen/Butalbital/Caffeine 300/50/40 mg & 325/50/40 mg capsule (Fioricet™, Esgic™)	No restriction
Fentanyl 50, 75, 100 mcg/hr patches	Limited to: • Hospital use (outpatient & ED) • Up to 1 patch per 3 days
Analeptic Agents	
Caffeine/Sodium Benzoate 125 mg-125 mg/ml, single dose vial (SDV)	No restriction
Antiepileptic Agents	
Valproate sodium 100 mg/ml IV in 5 ml SDV	Note that PHC reimbursement is as 1 unit=1 full vial, providers are not to bill per ML.
Anti-Infectives: Antibiotic Agents	
Cefprozil 125 mg/5ml & 250 mg/5 ml powder for reconstitution in 50, 75, & 100 ml	Note that PHC reimbursement units are as 1 unit=1 full bottle (providers are not to bill per ml).
Cefadroxil 500 mg capsule or suspension, &1000 mg tablet	No restriction. Note that for suspension, PHC reimbursement units are as 1 unit=1 full bottle (providers are not to bill per ml).
Behavioral Health: Benzodiazepines	
Temazepam 7.5 mg, (Restoril™) capsule	No restriction
Alprazolam 0.25, 0.5, 1, & 2 mg (Xanax™), immediate-release & orally disintegrating tablet	Limited for hospital use (outpatient & ED)
Cardiovascular Agents	
Aspirin/Dipyridamole 25 mg-200 mg capsule (Aggrenox™)	No restriction
Clonidine Patch 0.1, 0.2, & 0.3 mg/day (Catapres-TTS, replaced once weekly)	Maximum dose: 0.6 mg per day: • 0.1 & 0.2 mg patches, allowed up to 3 per service date • 0.3 mg patches, allowed up to 2 per service date
Dermatology Agents	
Benzocaine/Menthol 20%-0.5% Spray (Dermoplast™)	Limited to ED claims only as an enhanced benefit, otherwise remains a non-benefit at other locations.
Zinc Oxide 20% ointment	No restrictions

Additions to NDC Covered Drugs (J3490/Z7610 Unclassified NDC Claims, continued	
Generic (Brand)	**Coverage Requirements/Limits**
Electrolyte Regulation Agents	
Sodium zirconium cyclosilicate 5 & 10 g packets (Lokelma™)	No restrictions
Lower Gastrointestinal Agents	
Mesalamine 400 mg DR (delayed release) tablet (Delzicol™) & 375 mg ER (extended release) capsule (Apriso™)	No restrictions
Lubiprostone 8 & 24 mcg capsules (Amitiza™)	No restrictions
Nutritional Agents	
Calcium/Chloride/Magnesium 110 mg-186.8 mg-64 mg (Mag 64™, OTC)	No restrictions
Ophthalmology Agents	
Timolol maleate 0.25 & 0.5%, 0.3 ml preservative free unit dose (Timoptic Ocudose™)	No restrictions
Otic Agents	
Carbamide peroxide 6.5% solution (Murine Ear™ drops & kit, Debrox™ drops)	No restrictions