Brand/Trade names are shown for reference purposes only. Criteria apply to the generic product when a generic equivalent has been approved by the FDA. Additional criteria apply to brand name requests (when a generic is available), per PHC Policy *#MPRP4033.*

Daptomycin (Cubicin)	Pavalizumab (Synagis)	Ublituximab (Briumvi)	Ocrelizumab (Ocrevus)
Romiplostim (Nplate)	Luspatercept-aamt (Reblozyl)	Filgrastim (Neupogen)	Pegfilgrastim (Neulasta, Neulasta Onpro
Pegfilgrastim-fpgk (Stimufend)	Crizanlizumab-tmca (Adakveo)	Eculizumab IV (Soliris)	Ravulizumab IV (Ultomiris)
Oritavancin (Orbactiv),	Mesylate (Camcevi)	Posaconazole (Noxafil)	Valoctocogene roxaparvovec (Roctavian)
Dalbavancin (Dalvance)	Eflapegrastim (Rolvedon)	Tedizolid (Sivextro)	Standard Requirements for Antifungal Agents
Case-by-Case TAR Requirements and Considerations	Chimeric Antigen Receptor T-cell (CAR-T) Therapy: Abecma™ Breyanzi™ Carvykti™ Kymriah™ Tecartus™ Yescarta™		

Requirements for Pavilizumab injection (Synagis™)

Unless otherwise specified as having renewal requirements, criteria apply to new starts only. Include documentation of continuation of care if member is not new to treatment. Unless otherwise specified, brand names are shown for reference only and the criteria apply to the generic drug ingredient regardless of manufacturer or labeler.

PA Criteria	Criteria Details
Covered Uses	• For respiratory syncytial virus (RSV) infection prophylaxis to prevent serious infection of the lower respiratory tract in pediatric patients at high risk of RSV disease, including those with hemodynamically significant congenital heart disease
Exclusion Criteria	• Infant has already received nirsevimab (Beyfortus) within the same RSV season • Infants born greater than 29 wks without documentation of significant chronic lung disease, congenital heart disease, neuromuscular/other anomaly impairing upper airway clearance or severe immunodeficiency. • Infants born before 29 wks who are older than 12 months at the start of RSV season

Required Medical Information	1. Documentation of contraindication to nirsevimab (Beyfortus) or reasons why Beyfortus cannot be used
	2. Gestational age
	3. Birth weight
	4. Current weight
	5. Documentation that the infant is at high risk of hospitalization from RSV infection, such as infants who are:
	  ○ Born before 29 weeks, 0 days of gestation who are younger than 12 months at the start of RSV season.
	  ○ Younger than 12 months with CLD of prematurity, defined as gestational age less than 32week/0d and required greater than 21% oxygen for 28 days or more after birth.
	  ○ Aged 12-24 months with CLD of prematurity AND continue to require medical support during the 6 month period prior to RSV season.
	  ○ Children 12 months or younger with hemodynamically significant congenital heart disease (including those with acyanotic disease & receiving Rx to control CHF & will require surgical intervention, moderate to severe PAHT, acyanotic disease and request is made in conjunction with a pediatric cardiologist.
	  ○ Children younger than 24 months who undergo cardiac transplant during the RSV season.
	  ○ In addition, certain scenarios are evaluated on a case-by-case basis:
	  ▪ children less than 12 months with neuromuscular disease or congenital anomaly which impairs ability to clear secretions from the upper airway.
	  ▪ Infants & children with severe immunodeficiencies.

Age Restriction	Per criteria/policy (dependent upon gestational age at birth, age at start of RSV season and other risk factors present)
Prescriber Restriction	None
Coverage Duration	Per current CDC recommendations (usually not to exceed 5 doses or the end of RSV season).
Other Requirements & Information	Requests for off-label use: See PHC criteria document *Case-by-Case TAR Requirements and Considerations.*

Requirements for Pavilizumab injection (Synagis™)

Medical Billing:

Dose limits & billing requirements, with an approved TAR:

HCPCS	Description	Dosing, Units
90378	Respiratory syncytial virus, monoclonal antibody, recombinant, for intramuscular use, 50 mg, each (Synagis)	15mg/kg once monthly throughout RSV season, up to 5 doses or as recommended by the CDC.

Case-by-Case TAR Requirements and Considerations

Unless otherwise specified as having renewal requirements, criteria apply to new starts only. Include documentation of continuation of care if member is not new to treatment. Unless otherwise specified, brand names are shown for reference only and the criteria apply to the generic drug ingredient regardless of manufacturer or labeler.

PA Criteria	Criteria Details
Covered Uses	Covered uses (approvable diagnoses) are limited to FDA approved indications, unless off-label requirements are met. See "Other Criteria" below for off-label requirements. FDA approved uses can be found at: • https://dailymed.nlm.nih.gov/dailymed/index.cfm • https://www.pdr.net/ • https://nctr-crs.fda.gov/fdalabel/ui/search
Exclusion Criteria	1) Drugs or indications that are carved out to State Medi-Cal Fee-for-Service 2) Drugs that are excluded from reimbursement as stipulated by the State Plan, State Plan Amendments (SPA), All Plan Letters (APL), Centers for Medicare and Medicaid, &/or California Code of Regulations Title 22 3) TARs which lack adequate documentation of medical necessity or reasons why a preferred therapeutically equivalent agent cannot be used 4) Medications/doses that will be used at home, except when such use is allowed by contract or benefit type (eg, PHC Family Planning Benefit)
Required Medical Information	TAR must include an accurate diagnosis and include all necessary and relevant clinical documentation to support medical justification for the request, such as (but not limited to): 1) Clinic notes 2) Specialist consults 3) Lab reports (baseline, genetic markers, any recommended studies post-treatment initiation to monitor safety/efficacy, etc 4) Imaging reports if relevant 5) Reasons why preferred therapeutic alternatives (if any) cannot be used
Age Restriction	• Per FDA approved uses. • Consideration given for non-FDA-approved age(s) when requested by a specialist who is experienced in using the drug in the specialist's own scope of practice (eg, pediatric cardiologist, pediatric oncologist, pediatric neurologist, etc).
Prescriber Restriction	Appropriate specialist consult may be requested.
Coverage Duration	Determined based on condition being treated and by the information submitted with the TAR.
Other Requirements & Information	Case-by-case means that the medical necessity of the specific product for the individual member on a submitted TAR will be reviewed by considering the member's own medical history, such as: 1) Medication allergies 2) Disease history 3) Treatment history 4) Concurrent medications 5) Concurrent disease state(s) in combination, the member's medical need for urgent dose administration When a drug does not have established criteria, the request will fall under the category of case-by-review and in addition to the case-specific considerations listed above, the TAR request for the drug will be reviewed and approved or denied based on:

1) The prescriber's area of expertise or scope of practice.
2) FDA approved indications
3) National treatment guidelines
4) Availability of preferred therapeutic alternatives, cost effectiveness, &/or PHC policies that have specific guidance on coverage of drug therapies.

In addition to the above, the plan may use other clinical resources, including (but not limited to):

- Lexi-Drug
- Elsevier/Gold Standard Clinical Pharmacology
- NCCN (National Comprehensive Cancer Network)
- UpToDate
- Facts and Comparisons
- State Medi-Cal Fee-For-Service TAR requirements
- CCS (California Children's Services Numbered Letters (CCS TAR requirements)
- Manufacturer's package labeling
- Pre-market clinical trials on which FDA-approval was based
- Post-market clinical trials with additional evidence (or lack of evidence) of safety & efficacy of the requested drug, especially for drugs that were contingently approved through the FDA's accelerated pathway
- Post-market clinical trials with evidence supporting the use of a PHC preferred alternative to the requested drugs, including uses that are off-label but have been well established as an accepted use

Trial of preferred therapeutic alternatives: There is no set number of preferred medications that must be tried before a non-preferred medication can be approved, because it depends on each drug as to how many treatment alternatives are available, the pharmacologic and therapeutic similarities between the different treatments, and also depends greatly on the member's reason for failure with any alternatives that have been tried. Sometimes there are numerous alternatives for a particular drug, and other times only one or two. The number of trials required will be based on the clinical judgement of the physician or clinical pharmacist reviewer. Clinical documentation or laboratory evidence supporting an established contraindication to preferred treatment alternative(s) may be required for those who are unable to use preferred alternative(s).

Off-Label (Unlabeled) Uses:
The regulatory body that oversees Medi-Cal programs, DHCS (California Department of Health Care Services) has issued the following regarding the use of FDA-approved drugs for indications (diseases or conditions) that have not been approved for use by the FDA:

Per Title 22 CCR 51313 (4) Authorization for unlabeled use of drugs shall not be granted unless the requested unlabeled use represents reasonable and current prescribing practices. The determination of reasonable and current prescribing practices shall be based on:

A. Reference to current medical literature.
B. Consultation with provider organizations, academic and professional specialists.

Off-label use of medications not approved by the FDA for the diagnosis in question is not covered unless:

- FDA approved alternatives have first been medically ruled out (cannot be used in a particular situation for medical reasons such as allergy, serious drug interactions, previous adverse effects, or other contraindications).
- There are no FDA approved alternatives and the medication requested is the least costly treatment that is demonstrated to be possibly effective in treating the diagnosed condition.

Case-by-Case TAR Requirements and Considerations

	This is a reminder that only medication [services] approved by the FDA for the indication listed as the diagnosis can be [reimbursed], unless the use of that drug can be medically ruled out. Off-label use has been the source of lawsuits, manufacturer prosecution from the DOJ, and manufacturer disputes of rebates.

Medical Billing:
The requested quantity must be for the smallest volume necessary for the required dose, using the smallest size packaging available for the requested dose to avoid or minimize waste.

HCPCS Codes: When a drug has a specific HCPCS code, only the specific code is accepted for TARs and claims.

NOC codes: NOC=Not Otherwise Classified. NOC drugs are those that have not been assigned a drug-specific code by CMS, and are also referred to as "Unclassified drugs".. NOC *codes* are sometimes called "Miscellaneous Codes".By definition, NOC codes are not drug-specific., but there are varying levels of *drug type* specificity available for MEDICARE claims; however, PHC uses a limited number of NOC codes for TARs and claims.

Regardless of what NOC code a provider finds for a drug in a CMS HCPC code reference source,,
PHC only accepts the drug NOC codes indicated in the chart below:

CMS NOC Code	Code Description	
CMS NOC Codes Accepted by PHC:		**Comments:**
A9698	Non-radioactive contrast imaging material, not otherwise classified, per study dose	Invoice required with claims to determine pricing
A9699	Radiopharmaceutical, therapeutic, not otherwise classified	
J3490	Unclassified drugs	
J3590	Unclassified biologics	PHC allows either J3490 or J3590 for biologics, no preference. Biologics do require a TAR regardless of the code used. The code on the TAR must also be the code use for claims subsequent to an approved TAR.
S5000	Prescription drug, generic	These codes are used only for the Family Planning and Wellness & Recovery benefits.
S5001	Prescription drug, brand	
Z7610	Miscellaneous drugs and medical supplies	For *drugs*, Z7610 and J3490 are interchangeable. For supplies, Z7610 should be used.
CMS NOC Codes NOT ACCEPTED by PHC: Must use J3490 instead:		
C9399	Unclassified drugs or biologicals	
J7599	Immunosuppressive drug, not otherwise classified	
J7699	Not otherwise classified drugs, inhalation solution administered through DME	
J7799	Not otherwise classified drugs, other than inhalation drugs, administered through DME	
J7999	Compounded drug, not otherwise classified	
J8498	Antiemetic drug, rectal/suppository, not otherwise classified	
J9999	Not otherwise classified, antineoplastic drug	
90749	Unlisted vaccine/toxoid	
J3535	Drug administered through a metered dose inhaler	
J8499	Prescription drug, oral, non-chemotherapeutic, nos	
J8597	Antiemetic drug, oral, not otherwise specified	
J8999	Prescription drug, chemotherapeutic, nos	

Case-by-Case TAR Requirements and Considerations

Medical Billing, continued:

Billing Units: Pricing & units is dependent on how the product is packaged:

Dosage Form	Unit equivalence
Tablets, Capsules	1 tablet/capsule = 1 unit
Vials	System default: 1 vial=1 unit, regardless of size • Single-dose vials: Paid per vial; the submitted count should be the # of vials, rather than the # of ML. • Multi-dose, multi-patient vial: flagged for manual pricing, to be paid using ML pricing rather than full vial price.
IV bags	1 bag=1 unit, regardless of size
Oral liquids	System default: 1 full bottle or unit dose cup/syringe=1 unit, regardless of size • Single-patient use, such as reconstituted antibiotics: 1 unit is reimbursed as the full package size. Submitted count should be 1 per bottle, rather than the # of ML. • Multi-patient use, such as bulk bottles for pharmacy stock, dispensed out in smaller sizes for individual patient use (eg, 480 ml syrups): flagged for manual pricing, to be paid using ML pricing rather than by full package price.
Oral Inhalers (metered dose inhalers, dry powder inhalers)	Dependent on type. See PHC's MDL search tool for specific inhaler unit information. In general, aerosol/HFA types are reimbursed as 1 unit=1 inhaler and disk/dry powder inhalers are 1 unit=1 inhalation.

The following fall under the DHCS provider manual policies regarding double-billing, meaning payment as separate line items may not be allowed even when using the correct NOC or specific billing code, and even with an approved TAR:

Anesthesia-related drugs, including local/regional anesthetics, general anesthesia, anesthesia adjuncts such as neuromuscular blockade, sedatives, analgesics, and reversal agents	These are not separately payable when the provider will be submitting a UA/UB modifier with a surgical CPT code because the modifier includes all drug reimbursement. This includes anesthesia-related drugs which require a TAR – TAR authorization does not guarantee payment in addition to the UA/UB modifier.
Ophthalmic eye drops, visual aids	These are not separately payable when the provider will be submitting a UA/UB modifier on a cataract-related surgical CPT because the UA/UB modifier includes drug reimbursement.
Imaging agents (contrast, dyes)	Not payable as separate line items when the diagnostic CPT code includes the rate for the contrast/imaging agent.

Requirements for Ocrelizumab (Ocrevis™) and Ublituximab (Briumvi™)

Unless otherwise specified as having renewal requirements, criteria apply to new starts only. Include documentation of continuation of care if member is not new to treatment. Unless otherwise specified, brand names are shown for reference only and the criteria apply to the generic drug ingredient regardless of manufacturer or labeler.

PA Criteria	Criteria Details
Covered Uses	Treatment of relapsing forms of multiple sclerosis (MS), including clinically isolated syndrome (CIS), relapsing-remitting disease, and active secondary progressive disease in adults.
Exclusion Criteria	• History of life-threatening infusion reaction to ocrelizumab or ublituximab. • Active hepatitis B virus (HBV) infection. • Concurrent use of other disease-modifying therapies or immunosuppressives.
Required Medical Information	New Start: Clinical evaluation by neurologist with documentation of the following: • Diagnosis of relapsing form of MS, to include CIS, relapsing-remitting disease, and active secondary progressive disease as confirmed by brain MRI reports, lab reports, documentation of any planned diagnostic workup that has not yet been completed. MRI must show at least one demyelinating event. Submission of CSF study with oligoclonal banding &/or other diagnostic workup results (such as spinal MRI) should be included if brain MRI report is inconclusive. • Documentation that member does not have an active hepatitis B infection (as confirmed by Hepatitis B Surface Antigen [HBsAg] and anti-HBV tests). For patients who are negative for HBsAg and positive for Hepatitis B core antibody [HBcAb+] or are carriers of HBV [HBsAg+], consultation with liver disease experts before starting and during treatment is required. Renewals: Include any diagnostic workup that was still pending at time of prior request (additional imaging, CSF evaluation, etc.) and/or documentation of clinical response with therapy requested.
Age Restriction	Minimum Age: 18 years
Prescriber Restriction	Must be prescribed or recommended by a Neurologist
Coverage Duration	3 months when additional diagnostic workup is pending. 12 months if all supporting documentation is complete at time of initial TAR submission. Renewals for continuation of care with documentation of positive clinical response: 12 months
Other Requirements & Information	Requests for off-label use: See PHC criteria document *Case-by-Case TAR Requirements and Considerations.*

Requirements for Ocrelizumab (Ocrevis™) and Ublituximab (Briumvi™)

Medical Billing:

Dose limits & billing requirements, with an approved TAR:

HCPCS	Description	Dosing, Units
J2350	Injection, Ocrelizumab, 1 mg	Initial Dose: 300 mg once on day 1, followed by 300 mg once 2 weeks later; Subsequent doses, starting 6 months after 1 st infusion: – 600 mg every 6 months
J2329	Injection, ublituximab-xiiy, 1 mg	Initial Dose: 150 mg once on day 1, followed by 450 mg once 2 weeks later; Subsequent doses of 450 mg are administered once every 24 weeks (beginning 24 weeks after the first dose of 150 mg)

Requirements for Daptomycin (Cubicin™)

Unless otherwise specified as having renewal requirements, criteria apply to new starts only. Include documentation of continuation of care if member is not new to treatment. Unless otherwise specified, brand names are shown for reference only and the criteria apply to the generic drug ingredient regardless of manufacturer or labeler.

PA Criteria	Criteria Details
Covered Uses	• Complicated skin and skin structure infections (cSSSI) caused by susceptible isolates of the following Gram-positive bacteria: *Staphylococcus aureus* (including methicillin-resistant isolates), *Streptococcus pyogenes, Streptococcus agalactiae, Streptococcus dysgalactiae subsp. equisimilis*, and *Enterococcus faecalis* (vancomycin-susceptible isolates only) • *Staphylococcus aureus* bloodstream infections (bacteremia), including those with right-sided infective endocarditis, caused by methicillin susceptible and methicillin-resistant isolates.
Exclusion Criteria	• Pneumonia • Left-sided infective endocarditis • Infections in which IV treatment is not indicated
Required Medical Information	All Diagnoses: 1) Culture and Sensitivity lab report(s) when appropriate 2) Patient Med Allergy list if relevant 3) Treatment history for same infection 4) Clinic notes (or hospital admit and discharge) with assessment and plan <u>Complicated skin and skin structure infections</u>: 1) Documentation of trial and failure (or contraindication) to oral antibiotics appropriate to treat condition, such as: • Doxycycline • Minocycline • SMZ/TPM (Septra DS) • Erythromycin • Penicillins • Cephalosporins <u>MRSA (either cSSSI or bacteremia)</u> 1) IV treatment must be indicated 2) An Infectious Disease consult may be required
Age Restriction	≥ 1 year
Prescriber Restriction	None
Coverage Duration	Duration depends on diagnosis and treatment plan
Other Requirements & Information	Requests for off-label use: See PHC criteria document *Case-by-Case TAR Requirements and Considerations.*

Requirements for Daptomycin (Cubicin™)

Medical Billing:

Dose limits & billing requirements, with an approved TAR:

<table>
<tr><th>Product</th><th>HCPCS</th><th>Description</th><th>Dosing, Units</th></tr>
<tr><td>Cubicin</td><td>J0878</td><td>Injection, daptomycin, 1 mg</td><td rowspan="2">Weight based dosing, administered once every 24 hours
<table>
<tr><th>Age</th><th>cSSSI (7-14 days)</th><th>Bacteremia (2-6 weeks)</th></tr>
<tr><td>>17 yrs</td><td>4mg/kg</td><td>6mg/kg</td></tr>
<tr><td>12-17 yrs</td><td>5mg/kg</td><td>7mg/kg</td></tr>
<tr><td>7-11 yrs</td><td>7mg/kg</td><td>9mg/kg</td></tr>
<tr><td>2-6 yrs</td><td>9mg/kg</td><td rowspan="2">12mg/kg</td></tr>
<tr><td>1-<2 yrs</td><td>10mg/kg</td></tr>
</table></td></tr>
<tr><td>daptomycin</td><td>J0877</td><td>Injection, daptomycin (hospira), not therapeutically equivalent to J0878, 1 mg</td></tr>
</table>

Requirements for Valoctocogene roxaparvovec-rvox (Roctavian™)

Unless otherwise specified as having renewal requirements, criteria apply to new starts only. Include documentation of continuation of care if member is not new to treatment. Unless otherwise specified, brand names are shown for reference only and the criteria apply to the generic drug ingredient regardless of manufacturer or labeler.

PA Criteria	Criteria Details
Covered Uses	Treatment of adults with severe hemophilia A who have congenital favor VIII deficiency with factor VIII activity <1IU/dL
Exclusion Criteria	1. Treatment or use for anything other than hemophilia A 2. Previous gene therapy treatment with valoctocogene roxaparvovec-rvox (Roctavian) 3. Active infection, either acute or uncontrolled chronic 4. Significant hepatic fibrosis (stage 3 or 4), or cirrhosis 5. Presence of factor VIII inhibitors 6. Positive AAV5 antibody test
Required Medical Information	1) Documentation of severe hemophilia A as evidenced by congenital factor VIII deficiency with factor VIII activity <1 IU/dL 2) Documentation of a negative AAV5 antibody test result using an FDA approved test 3) Documentation of two consecutive negative factor VIII inhibitor tests at least 1 week apart within the previous 12 months 4) Liver function tests: ALT, AST, GGT, ALP, total bilirubin, INR, ultrasound and elastography or laboratory assessment for liver fibrosis 5) Policy MCUP3138 External Independent Medical Review will apply, enabling Partnership to obtain a specialist's evaluation of the case prior to both denials and approvals (ie denials for medical necessity).
Age Restriction	≥18 years
Prescriber Restriction	Hematologist
Coverage Duration	Once per lifetime
Other Requirements & Information	Allowed for once in a lifetime treatment. There will be no renewals or retreatment requests approved.

Medical Billing:

Dose limits & billing requirements, with an approved TAR:

HCPCS	Description	Dosing, Units
J3590 (NOC)	Unclassified Biologics (Roctavian)	Dose: $6x10^{13}$ vector genomes (vg)/kg. Supplied as a $2x10^{13}$vg/ml suspension, each vial contains at least 8ml ($16x10^{13}$ vg) Each vial is single dose.

Requests for off-label use: See PHC criteria document Case-by-Case TAR Requirements and Considerations.

Requirements for Valoctocogene roxaparvovec-rvox (Roctavian™)

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Requirements for Romiplostim injection (Nplate™)

Unless otherwise specified as having renewal requirements, criteria apply to new starts only. Include documentation of continuation of care if member is not new to treatment. Unless otherwise specified, brand names are shown for reference only and the criteria apply to the generic drug ingredient regardless of manufacturer or labeler.

PA Criteria	Criteria Details
Covered Uses	• Immune thrombocytopenia (ITP) with risk for bleeding • Hematopoietic Syndrome of Acute Radiation Syndrome (H-ARS)
Exclusion Criteria	• Used to normalize platelet count

Required Medical Information	Requirements for Immune thrombocytopenia (ITP)
	• Clinical documentation to confirm diagnosis of ITP with platelet count <30,000/microL, or platelets count between 30,000 – 50,000/microL in patients with high risk for bleeding (peptic ulcer, use of anticoagulants, high risk of falling) vs malignancy or other determinate cause of thrombocytopenia
	• Documentation, including length of treatment and labs to confirm inadequate response or reason(s) for failure/clinical contraindication to treatment with ALL of the following
	  ○ Oral glucocorticoids
	  ○ IVIG (e.g. Gammagard™) or AntiD immunoglobulin [Rho(D) immune globulin]
	  ○ Eltrombopag (Promacta) or avatrombopag (Doptelet)
	  ○ Splenectomy
	• Current weight, within past 30 days of request.

Age Restriction	≥ 1 year
Prescriber Restriction	Must be prescribed or recommended by a hematologist
Coverage Duration	Initial: 2 months Renewal: 6 months
Other Requirements & Information	Renewal Requirements: current CBC included to indicate benefit with treatment Requests for Hematopoietic Syndrome of Acute Radiation Syndrome (H-ARS) and off-label use: See PHC criteria document *Case-by-Case TAR Requirements and Considerations.*

Requirements for Romiplostim injection (Nplate™)

Medical Billing:

Dose limits & billing requirements, with an approved TAR:

HCPCS	Description	Dosing, Units
J2796	Injection, romiplostim, 10 micrograms (Nplate)	Initial: 1mcg/kg (using actual body weight) Adjust the weekly dose of Nplate by increments of 1 mcg/kg until the patient achieves a platelet count ≥ 50k cells/L as necessary to reduce the risk for bleeding; do not exceed a maximum weekly dose of 10 mcg/kg Adjust the dose as follows: • If the platelet count is <50k, increase the dose by 1 mcg/kg. • If platelet count is >200k and ≤400k for 2 consecutive weeks, reduce the dose by 1 mcg/kg. • If platelet count is > 400k, do not dose. Continue to assess the platelet count weekly. After the platelet count has fallen to < 200k, resume Nplate at a dose reduced by 1 mcg/kg. Nplate should be discontinued if an increase in platelet count has not been achieved after 4 weeks at maximum allowed/tolerated dose for ITP

Requirements for Lucpatercept-aamt (Reblozyl™)

Unless otherwise specified as having renewal requirements, criteria apply to new starts only. Include documentation of continuation of care if member is not new to treatment. Unless otherwise specified, brand names are shown for reference only and the criteria apply to the generic drug ingredient regardless of manufacturer or labeler.

PA Criteria	Criteria Details
Covered Uses	• Anemia in adults with beta (β) thalassemia who require regular RBC transfusions. • Myelodysplastic syndromes with ring sideroblasts (MDS-RS) or Myelodysplastic/myeloproliferative neoplasm with ring sideroblasts and thrombocytosis (MDS/MPN-RS-T).
Exclusion Criteria	• Non-transfusion dependent β-thalassemia • Treatment of other causes of anemia • Deep vein thrombosis or stroke within the past 24 weeks prior to start of treatment • Pregnant or breastfeeding
Required Medical Information	For initial requests: 1) Clinic notes to confirm the diagnosis with one of the following: • β–thalassemia • Myelodysplastic Syndrome with ring sideroblasts (MDS-RS) • Myelodysplastic/myeloproliferative neoplasm with ring sideroblasts and thrombocytosis (MDS/MPN-RS-T) 2) Other causes of anemia (e.g. bleeding, vitamin deficiency, iron deficiency, acute leukemia) have been ruled out. 3) Weight (kg, lb) 4) Requirement for those with a confirmed diagnosis of β–thalassemia: • Transfusion records to showing member is transfusion dependent, as evidenced by both of the following within the past 24 weeks: ○ Requires regular RBC transfusions with ≥ 6 units of packed red blood cells (PRBC) AND ○ No transfusion free period ≥ 35 days ○ Serum ferritin levels >1,000 ng/ml 5) Requirements for those with a confirmed diagnosis of MDS-RS or MDS/MPN-RS-T: • Documented lower risk disease as defined by one of the following: ○ Revised International Prognostic Scoring System (IPSS-R) - Very Low, Low, Intermediate (Score 0 to ≤ 4.5) ○ IPSS - Low/Intermediate-1 (Score 0 to 1) ○ WHO-Based Prognostic Scoring System (WPSS) - Very Low, Low, Intermediate (Score 0 to 2) • Documentation of either: ○ Ring sideroblasts ≥ 15% OR ○ Ring sideroblasts ≥ 5% with an SF3B1 mutation • Non-responsive to or intolerant to erythropoiesis stimulating agents (ESA) or ESA is not indicated due to serum erythropoietin > 200 mU/mL • Patient requires at least 2 units of packed red blood cells (pRBCs) in the prior 8 weeks
Age Restriction	18 years and older
Prescriber Restriction	Must be prescribed or recommended by a Hematologist or Hematologist–Oncologist

Requirements for Lucpatercept-aamt (Reblozyl™)

Coverage Duration	Initial approval: 6 months Renewal: up to 12 months
Other Requirements & Information	Documentation requirement for renewal: • Decrease in transfusion burden after 3 maximally tolerated doses (9 weeks of treatment). *Note: Treatment should be discontinued if there has not been a reduction in transfusion requirements per manufacturer's recommendation.* Requests for off-label use: See PHC criteria document *Case-by-Case TAR Requirements and Considerations.*

Medical Billing:

Dose limits & billing requirements, with an approved TAR:

HCPCS	Description	Dosing, Units
J0896	Injection, luspatercept-aamt, 0.25 mg	β-thalassemia: 1 mg/kg SC q3weeks Max dose: 1.25 mg/kg q3weeks MDS-RS or MDS/MPN-RS-T: 1 mg/kg SC q3weeks Max dose: 1.75 mg/kg q3weeks

Recommended dosing adjustment based on hemoglobin (Hgb) level (per manufacturer package insert:

1) Predose hemoglobin ≥11.5 g/dL (in the absence of transfusions): Interrupt luspatercept; resume when hemoglobin is ≤11 g/dL.

2) Increase Hgb > 2 g/dl within 3 weeks (in absence of transfusions):

β – Thalassemia	
Current Dose	Reduce to x mg/kg once every 3 weeks
1.25 mg/kg	1 mg/kg
1 mg/kg	0.8 mg/kg
0.8 mg/kg	0.6 mg/kg
0.6 mg/kg	*Discontinue*
MDS-RS or MDS/MPN-RS-T	
Current Dose	Reduce to x mg/kg once every 3 weeks
1.75 mg/kg	1.33 mg/kg
1.33 mg/kg	1 mg/kg
1 mg/kg	0.8 mg/kg
0.8 mg/kg	0.6 mg/kg
0.6 mg/kg	*Discontinue*

Requirements for Crizanlizumab-tmca (Adakveo™)

Unless otherwise specified as having renewal requirements, criteria apply to new starts only. Include documentation of continuation of care if member is not new to treatment. Unless otherwise specified, brand names are shown for reference only and the criteria apply to the generic drug ingredient regardless of manufacturer or labeler.

PA Criteria	Criteria Details
Covered Uses	Sickle Cell Disease
Exclusion Criteria	None
Required Medical Information	1) Current weight (kg) within the last 4 weeks, submitted with initial request and each renewal request. 2) Number of events in the past 365 days, prior to treatment with Adakveo. 3) Documentation of an inadequate response after at least a 3-month trial each of both hydroxyurea AND L-glutamine (Endari) despite compliant use. An inadequate response would be demonstrated when the member continues to have >2 events annually or no decrease in number of events prior to starting the medication.
Age Restriction	16 years and older
Prescriber Restriction	Must be prescribed or recommended by a hematologist
Coverage Duration	6 months
Other Requirements & Information	Renewal requests: Current weight (kg) within the last 4 weeks and benefit to treatment such as reduction of events. Requests for off-label use: See PHC criteria document *Case-by-Case TAR Requirements and Considerations.*

Medical Billing:

Dose limits & billing requirements, with an approved TAR:

HCPCS	Description	Dosing, Units
J0791	Injection, crizanlizumab-tmca, 5 mg (Adakveo™)	Initial dosing limited to 5 mg/kg on week 0 and week 2. Maintenance dosing limited to 5 mg/kg once every 4 weeks. For missed doses – if administered within 2 weeks after missed dose, continued dosing according to original schedule, however if missed dose is administered greater than 2 weeks then then continue dosing every 4 weeks using last date of dosing

Requirements for Filgrastim (Neupogen™)

Unless otherwise specified as having renewal requirements, criteria apply to new starts only. Include documentation of continuation of care if member is not new to treatment. Unless otherwise specified, brand names are shown for reference only and the criteria apply to the generic drug ingredient regardless of manufacturer or labeler.

PA Criteria	Criteria Details
Covered Uses	• Prevention or treatment of chemotherapy-induced neutropenia. • Acute myeloid leukemia (AML) following induction or consolidation chemotherapy • Bone marrow transplantation (BMT) • Severe chronic neutropenia • Peripheral blood progenitor cell collection and therapy • Hematopoietic Syndrome of Acute Radiation Syndrome [HARS]
Exclusion Criteria	None
Required Medical Information	For prevention or treatment of chemotherapy-induced neutropenia: Requests must include clinic notes documenting • Diagnosis • Specific chemotherapy regimen with dose and frequency • Current and past absolute neutrophil count (ANC) lab report documenting history of severe neutropenia secondary to chemotherapy (if applicable) • Member-specific risk factors for developing neutropenia (if any). For chemotherapy regimens not identified as having high risk (greater than 20%) or intermediate risk (10-20%) of febrile neutropenia (FN) in the absence of any associated patient risk factors, clinical literature supporting intermediate to high risk of FN may be required. For all other indications or off-label use: Requests must include accurate diagnosis as provided by prescriber, all necessary/relevant clinical documentation to support medical justification (e.g. clinic notes, lab reports including absolute neutrophil count (ANC), specialist consults, insurance approval of stem cell transplant, etc).
Age Restriction	Per FDA package labeling or accepted off-label use.
Prescriber Restriction	Prescribed by, or in consultation with, an oncologist or hematologist.
Coverage Duration	TBD based on chemotherapy regimen, up to a maximum of 6 months per authorization.

Requirements for Filgrastim (Neupogen™)

Other Requirements & Information	1) For treatment of chemotherapy-induced neutropenia: clinical documentation supporting inadequate response with preferred Filgrastim-sndz (Zarxio), Filgrastim-ayoq (Releuko) and Filgrastim-aafi (Nivestym) with laboratory evidence or medical rationale as to why Zarxio, Releuko and Nivestym cannot be used must be provided. 2) For prevention of chemotherapy-induced neutropenia, clinical documentation supporting inadequate response with preferred Zarxio, Releuko and Nivestym AND Tbo-Filgrastim (Granix) with laboratory evidence or medical rationale as to why Zarxio, Releuko and Nivestym AND Granix cannot be used must be provided. ALSO must meet ONE of the following: a. Primary prophylaxis of febrile neutropenia in member receiving myelosuppressive chemotherapy with an expected incidence of febrile neutropenia of >20% (high risk) or at least 10-20% (intermediate risk) if member has at least 1 risk factor for developing neutropenia as summarized in the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines) for use of Myeloid Growth Factors. b. Secondary prophylaxis of febrile neutropenia in member who experienced neutropenic complication from prior chemotherapy and did not receive primary prophylaxis with a myeloid growth factor and a reduced dose or frequency of chemotherapy may compromise treatment outcome. c. Treatment of febrile neutropenia in patients who received chemotherapy and have at least one risk factor for poor clinical outcomes or for developing infection-associated complications as summarized in the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines) for use of Myeloid Growth Factors. NOTE: There are no studies that have addressed therapeutic use of Filgrastim for febrile neutropenia in patients who have already received prophylactic pegfilgrastim. However, pharmacokinetic data of pegfilgrastim demonstrated high levels during neutropenia and suggest that additional granulocyte colony-stimulating factors (G-CSF) may not be beneficial, but in patients with prolonged neutropenia additional G-CSF may be considered. Requests for other indications and off-label use: See PHC criteria document *Case-by-Case TAR Requirements and Considerations.*

Medical Billing:

Dose limits & billing requirements, with an approved TAR:

Product	HCPCS	Description	Dosing, Units
Neupogen	J1442	Injection, filgrastim (g-csf), excludes biosimilars, 1 microgram	5-10mcg/kg/day, duration based on ANC response / indication

Requirements for Eflapegrastim (Rolvedon™)

Unless otherwise specified as having renewal requirements, criteria apply to new starts only. Include documentation of continuation of care if member is not new to treatment. Unless otherwise specified, brand names are shown for reference only and the criteria apply to the generic drug ingredient regardless of manufacturer or labeler.

PA Criteria	Criteria Details
Covered Uses	Prevention of chemotherapy-induced neutropenia
Exclusion Criteria	• Use for the mobilization of peripheral blood progenitor cells for hematopoietic stem cell transplantation. • Dosed more frequently than every 14 days for prevention of chemotherapy-induced neutropenia.
Required Medical Information	Clinic notes documenting: • Diagnosis • Specific chemotherapy regimen with dose and frequency • Current and past absolute neutrophil count (ANC) lab report documenting history of severe neutropenia secondary to chemotherapy (if applicable) • Member specific risk factors for developing neutropenia (if any) For chemotherapy regimens not identified as having high risk (greater than 20%) or intermediate risk (10-20%) of febrile neutropenia (FN) in the absence of any associated patient risk factors, clinical literature supporting intermediate to high risk of FN may be required.
Age Restriction	≥ 18 years
Prescriber Restriction	Prescribed by, or in consultation with, an oncologist or hematologist.
Coverage Duration	TBD based on chemotherapy regimen
Other Requirements & Information	For prevention of chemotherapy-induced neutropenia, clinical documentation supporting inadequate response to pegfilgrastim must be provided. ALSO must meet ONE of the following: (1) Primary prophylaxis of febrile neutropenia in patients receiving myelosuppressive chemotherapy with an expected incidence of febrile neutropenia of greater than 20% (high risk) or at least 10-20% (intermediate risk) if patient has at least one risk factor for developing neutropenia as summarized in the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines) for use of Myeloid Growth Factors. OR (2) Secondary prophylaxis of febrile neutropenia in patients who experienced neutropenic complication from prior chemotherapy and did not receive primary prophylaxis with a myeloid growth factor and a reduced dose or frequency of chemotherapy may compromise treatment outcome. Requests for off-label use: See PHC criteria document *Case-by-Case TAR Requirements and Considerations.*

Requirements for Eflapegrastim (Rolvedon™)

Medical Billing:

Dose limits & billing requirements, with an approved TAR:

Product	HCPCS	Description	Dosing, Units
Rolvedon	J1449	Injection, eflapegrastim-xnst, 0.1 mg	13.2mg (132 HCPCS units) once per cycle of chemotherapy, not more often than 14 days

Requirements for Pegfilgrastim-fpgk (Stimufend™)

Unless otherwise specified as having renewal requirements, criteria apply to new starts only. Include documentation of continuation of care if member is not new to treatment. Unless otherwise specified, brand names are shown for reference only and the criteria apply to the generic drug ingredient regardless of manufacturer or labeler.

PA Criteria	Criteria Details
Covered Uses	• Prevention of chemotherapy-induced neutropenia.
Exclusion Criteria	• Use for the mobilization of peripheral blood progenitor cells for hematopoietic stem cell transplantation. • Dosed more frequently than every 14 days for prevention of chemotherapy-induced neutropenia.
Required Medical Information	Clinic notes documenting: • Diagnosis • Specific chemotherapy regimen with dose and frequency • Current and past absolute neutrophil count (ANC) lab report documenting history of severe neutropenia secondary to chemotherapy (if applicable) • Member specific risk factors for developing neutropenia (if any) For chemotherapy regimens not identified as having high risk (greater than 20%) or intermediate risk (10-20%) of febrile neutropenia (FN) in the absence of any associated patient risk factors, clinical literature supporting intermediate to high risk of FN may be required.
Age Restriction	None
Prescriber Restriction	Prescribed by, or in consultation with, an oncologist or hematologist.
Coverage Duration	TBD based on chemotherapy regimen, up to a maximum of 6 months per authorization.
Other Requirements & Information	For prevention of chemotherapy-induced neutropenia, clinical documentation supporting inadequate response to a preferred biosimilar product (Fulphila, Fylnetra, Nyvepria, Udenyca,or Ziextenzo) must be provided. ALSO must meet ONE of the following: (1) Primary prophylaxis of febrile neutropenia in patients receiving myelosuppressive chemotherapy with an expected incidence of febrile neutropenia of greater than 20% (high risk) or at least 10-20% (intermediate risk) if patient has at least one risk factor for developing neutropenia as summarized in the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines) for use of Myeloid Growth Factors. OR (2) Secondary prophylaxis of febrile neutropenia in patients who experienced neutropenic complication from prior chemotherapy and did not receive primary prophylaxis with a myeloid growth factor and a reduced dose or frequency of chemotherapy may compromise treatment outcome. Requests for off-label use: See PHC criteria document *Case-by-Case TAR Requirements and Considerations.*

Requirements for Pegfilgrastim-fpgk (Stimufend™)

Medical Billing:

Dose limits & billing requirements, with an approved TAR:

Product	HCPCS	Description	Dosing, Units
Stimufend	Q5127	Injection, pegfilgrastim-fpgk (stimufend) biosimilar, 0.5 mg	6mg (12 HCPCS units) once per cycle of chemotherapy, not more often than 14 days

Requirements for Pegfilgrastim (Neulasta, Neulasta Onpro™)

Unless otherwise specified as having renewal requirements, criteria apply to new starts only. Include documentation of continuation of care if member is not new to treatment. Unless otherwise specified, brand names are shown for reference only and the criteria apply to the generic drug ingredient regardless of manufacturer or labeler.

PA Criteria	Criteria Details
Covered Uses	• Prevention of chemotherapy-induced neutropenia. • Hematopoietic Syndrome of Acute Radiation Syndrome [H-ARS]
Exclusion Criteria	• Use for the mobilization of peripheral blood progenitor cells for hematopoietic stem cell transplantation. • Dosed more frequently than every 14 days for prevention of chemotherapy-induced neutropenia.
Required Medical Information	Clinic notes documenting: • Diagnosis • Specific chemotherapy regimen with dose and frequency • Current and past absolute neutrophil count (ANC) lab report documenting history of severe neutropenia secondary to chemotherapy (if applicable) • Member specific risk factors for developing neutropenia (if any) For chemotherapy regimens not identified as having high risk (greater than 20%) or intermediate risk (10-20%) of febrile neutropenia (FN) in the absence of any associated patient risk factors, clinical literature supporting intermediate to high risk of FN may be required.
Age Restriction	None
Prescriber Restriction	Prescribed by, or in consultation with, an oncologist or hematologist.
Coverage Duration	TBD based on chemotherapy regimen, up to a maximum of 6 months per authorization.
Other Requirements & Information	For prevention of chemotherapy-induced neutropenia, clinical documentation supporting inadequate response to a preferred biosimilar product (Fulphila, Fylnetra, Nyvepria, Udenyca,or Ziextenzo) must be provided. ALSO must meet ONE of the following: (1) Primary prophylaxis of febrile neutropenia in patients receiving myelosuppressive chemotherapy with an expected incidence of febrile neutropenia of greater than 20% (high risk) or at least 10-20% (intermediate risk) if patient has at least one risk factor for developing neutropenia as summarized in the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines) for use of Myeloid Growth Factors. OR (2) Secondary prophylaxis of febrile neutropenia in patients who experienced neutropenic complication from prior chemotherapy and did not receive primary prophylaxis with a myeloid growth factor and a reduced dose or frequency of chemotherapy may compromise treatment outcome. Requests for off-label use: See PHC criteria document *Case-by-Case TAR Requirements and Considerations.*

Requirements for Pegfilgrastim (Neulasta, Neulasta Onpro™)

Medical Billing:

Dose limits & billing requirements, with an approved TAR:

Product	HCPCS	Description	Dosing, Units
Neulasta, Neulasta Onpro	J2506	Injection, pegfilgrastim, excludes biosimilar, 0.5 mg	6mg (12 HCPCS units) once per cycle of chemotherapy, not more often than 14 days

Requirements for Eculizumab (Soliris™)

Unless otherwise specified as having renewal requirements, criteria apply to new starts only. Include documentation of continuation of care if member is not new to treatment.

PA Criteria	Criteria Details
Covered Uses	1) Atypical hemolytic uremic syndrome (aHUS) to inhibit complement mediated thrombotic microangiopathy. 2) Generalized myasthenia gravis (gMS) in adults who are anti-acetylcholine receptor antibody-positive (AChR+). 3) Neuromyelitis optica spectrum disorder (NMOSD) in adults who are aquaporin-4-antibody positive. 4) Paroxysmal nocturnal hemoglobinuria (PNH) to reduce hemolysis.
Exclusion Criteria	• Unresolved serious Neisseria meningitides infection • Treatment of Shiga toxin E. coli related hemolytic uremic syndrome • Myasthenia gravis MuSK antibody, LRP4 antibody positive or seronegative • Use along with ravulizumab (Ultomiris™) or efgartigimodum alfa-fcab (Vyvgart™) • NMOSD negative AQP4-IgG
Required Medical Information	1) <u>Requirements for atypical hemolytic uremic syndrome:</u> a. Appropriate labs to confirm diagnosis (e.g. Flow cytometry, CBC) b. Documentation of meningococcal vaccine given prior to therapy or will be given immediately after the first dose of the complement inhibitor. Weight (kg, lb) c. Documentation that Shiga toxin has been ruled out d. Trial and failure with ravulizumab (Ultomiris™) 2) <u>Requirements for paroxysmal nocturnal hemoglobinuria:</u> a. Appropriate labs to confirm diagnosis (e.g. Flow cytometry, CBC) b. Documentation of meningococcal vaccine given prior to therapy or will be given immediately after the first dose of the complement inhibitor. Weight (kg, lb) c. Trial and failure with ravulizumab (Ultomiris™) 3) <u>Requirement for those with a confirmed diagnosis of positive AChR, gMS:</u> a. Positive immunologic binding assay to confirm MG due to the presence of AChR antibodies. b. Documentation of meningococcal vaccine given prior to therapy or will be given immediately after the first dose of the complement inhibitor. c. Avoidance of drugs that may exacerbate MG if possible such as but not limited to: Beta-blockers, hydroxychloroquine, gabapentin, lithium. d. Myasthenia Gravis Activities of Daily Living (MG-ADL) score ≥ 6 at baseline. e. Myasthenia Gravis Foundation of America (MGFA) clinical classification of Class II to IV f. Documentation to indicated trial and failure (insufficient response) or reason(s) for contraindication to all of the following: i. Pyridostigmine ii. Moderate to high dose glucocorticoids (onset 2-3 weeks and peaks 5.5 months), tapered to the lowest effective dose iii. Oral glucocorticoid sparing immunomodulator, such as: azathioprine, cyclosporine, tacrolimus or mycophenolate iv. Efgartigimod alfa-fcab (Vyvgart™) AND Ravulizumab (Ultomiris™)

Requirements for Eculizumab (Soliris™)

	4) Requirements for Neuromyelitis optica spectrum disorder (NMOSD): a. At least one of the following: i. Optic neuritis Acute myelitis ii. Area postrema syndrome: Episode of otherwise unexplained hiccups or nausea and vomiting iii. Acute brainstem syndrome (acute inflammatory demyelination of the primary medulla) iv. Symptomatic narcolepsy or acute diencephalic clinical syndrome with NMOSD-typical diencephalic MRI lesions v. Symptomatic cerebral syndrome with NMOSD-typical brain lesions b. Seropositive for AQP4-IgG antibodies c. Documentation of trial and failure or contraindication: i. Satralizumab (Enspryng™) ii. OR Inebilizumab-cdon (Uplizna™)
Age Restriction	aHUS: 2 months of age and older gMS, NMOSD, PNH: 18 years and older
Prescriber Restriction	• PNH: Hematologist • aHUS: Nephrologist, Hematologist • gMS: Neurologist • NMOSD: Neurologist, Ophthalmologist *Note: Prescribers must be enrolled in REMS*
Coverage Duration	Initial TAR for loading dose: Approved for 1 to 4 loading doses, depending on indication and weight of the patient (if relevant) Initial TAR for maintenance dose: 6 months Renewal TAR: Approved for 1 dose per fill for up to 6 months.
Other Requirements & Renewal Information	Renewal Requests: • Clinical notes with current: o MG-ADL o MGFA classification Requests for off-label use: See PHC criteria document ***Case-by-Case TAR Requirements and Considerations.***

Requirements for Eculizumab (Soliris™)

Medical Billing:

Use is available only through the restricted Soliris™ REMS program.

Dose limits & billing requirements (approved TAR is required)

HCPCS	Description	Dosing, Units
J1300	Injection, Eculizumab, 10 mg	aHUS, gMS, NMOSD (≥ 18 yrs): • 900 mg IV qwk x 4 doses, then 1,200 mg for the 5th dose on week 5, then 1,200 mg q2wks thereafter. aHUS (≥ 2 months): PNH: • 600 mg IV qwk x 4 doses, then 900 mg for the 5th dose on week 5, then 900 mg q2wks thereafter.

aHUS (≥ 2 months):

Weight	Induction dose (qwk)	Maintenance dose
≥ 40 kg	900 mg x 4	1,200 mg at week 5, then q2wks
30 -39 kg	600 mg x 2	30 -39 kg 600 mg x2 900 mg at week 3, then q2wks
0 – 29 kg	600 mg x 2	600 mg at week 3, then q2wks
10 – 19 kg	600 mg x 1	300 mg at week 2, then q2wks
5 - 9 kg	300 mg x 1	300 mg at week 2 then q3wks

Requirements for Ravulizumab (Ultomiris™)

Unless otherwise specified as having renewal requirements, criteria apply to new starts only. Include documentation of continuation of care if member is not new to treatment.

PA Criteria	Criteria Details
Covered Uses	1) Atypical hemolytic uremic syndrome to inhibit complement mediated thrombotic microangiopathy. 2) Paroxysmal nocturnal hemoglobinuria. 3) Generalized myasthenia gravis (gMG) in adults who are anti-acetylcholine receptor antibody-positive (AChR+)
Exclusion Criteria	• Unresolved serious Neisseria meningitides infection • Treatment of Shiga toxin E. coli related hemolytic uremic syndrome • Myasthenia gravis MuSK antibody, LRP4 antibody positive or seronegative • Use along with Eculizumab (Soliris™) or efgartigimod alfa-fcab (Vyvgart™)
Required Medical Information	1) Requirements for atypical hemolytic uremic syndrome: a. Appropriate labs to confirm diagnosis (e.g. Flow cytometry, CBC) b. Documentation of meningococcal vaccine given prior to therapy or will be given immediately after the first dose of the complement inhibitor c. Weight (kg, lb) d. Documentation that Shiga toxin has been ruled out 2) Requirements for paroxysmal nocturnal hemoglobinuria: a. Appropriate labs to confirm diagnosis (e.g. Flow cytometry, CBC) b. Documentation of meningococcal vaccine given prior to therapy or will be given immediately after the first dose of the complement inhibitor c. Weight (kg, lb) 3) Requirement for AChR antibody-related myasthenia gravis a. Positive immunologic binding assay to confirm MG due to the presence of AChR antibodies b. Documentation of meningococcal vaccine given prior to therapy or will be given immediately after the first dose of the complement inhibitor. c. Avoidance of drugs that may exacerbate MG if possible such as but not limited to: Beta blockers, hydroxychloroquine, gabapentin, lithium d. Myasthenia Gravis Activities of Daily Living (MG-ADL) score ≥ 6 at baseline e. Myasthenia Gravis Foundation of America (MGFA) clinical classification of Class II to IV f. Documentation to indicated trial and failure (insufficient response) or reason(s) for contraindication to: • Pyridostigmine • Moderate to high dose glucocorticoids (onset 2-3 weeks and peaks 5.5 months), tapered to the lowest effective dose AND • Oral glucocorticoid sparing immunomodulator, such as: azathioprine, cyclosporine, tacrolimus or mycophenolate AND Efgartigimod alfa-fcab (Vyvgart™)

Requirements for Ravulizumab (Ultomiris™)

Age Restriction	aHUS and PNH: ≥ 1 months MG: ≥ 18 years
Prescriber Restriction	• aHUS: Nephrologist, Hematologist • PNH: Hematologist • MG: Neurologist *Note: Prescribers must be enrolled in REMS*
Coverage Duration	Initial: 6 months Renewal: 12 months

Other Requirements & Information	Renewal Requests:
	• Clinical notes with current:
	  ○ MG-ADL
	  ○ MGFA classification
	
	Requests for off-label use: See PHC criteria document *Case-by-Case TAR Requirements and Considerations*

Medical Billing:

Use is available only through the restricted Ultomiris™ REMS program.
Dose limits & billing requirements, with an approved TAR:

HCPCS	Description	Dosing, Units
J1303	Injection, Ravulizumab, 10mg	aHUS and PNH ≥ 1 month:

Weight	Loading Dose	Maintenance dose IV (start 14 days after loading dose)	Maintenance Interval
5 kg – 9 kg	600 mg	300 mg	4 weeks
10 kg – 19 kg	600 mg	600 mg	
20 kg – 29 kg	900 mg	2,100 mg	8 weeks
30 kg – 39 kg	1,200 mg	2,700 mg	
40 kg – 59 kg	2,400 mg	3,000 mg	
60 kg – 99 kg	2,700 mg	3,300 mg	
≥ 100 kg	3,000 mg	3,600 mg	

gMG ≥18 years:

Weight	Loading Dose	Maintenance dose IV (start 14 days after loading dose)	Maintenance Interval
40 kg – 59 kg	2,400 mg	3,000 mg	8 weeks
60 kg – 99 kg	2,700 mg	3,300 mg	
≥ 100 kg	3,000 mg	3,600 mg	

Standard Requirements for Antifungal Agents

(TAR review criteria when drug-specific criteria is not otherwise specified)

Unless otherwise specified as having renewal requirements, criteria apply to new starts only. Include documentation of continuation of care if member is not new to treatment.

PA Criteria	Criteria Details
Covered Uses	1) FDA approved indications 2) Accepted off-label indications/medically accepted indications: Defined as using the following standard reference compendia, such as but not limited to: • Infectious Diseases Society of America Guidelines • Centers for Disease Control and Prevention (CDC) • National Institute of Allergy and Infectious Diseases • American Academy of HIV Medicine • World Health Organization (WHO) • National Comprehensive Cancer Network (NCCN) • American Society of Transplantation (ATS)
Exclusion Criteria	Varies based on manufacturer requirements
Required Medical Information	Clinic notes which include: • Detailed treatment history including contraindication or failure of preferred, first-line treatment options which may include the following preferred alternatives such as: amphotericin B products - Amphotericin B desoxycholate, Abelcet, AmBisome, Amphotec (QL: 600 mg/day), micafungin (Mycamine). • Current treatment plan. • Anticipated duration of therapy.
Age Restriction	Dependent on FDA approved ages for treatment
Prescriber Restriction	Consultation or recommended by Infectious Disease, HIV specialist, Pulmonology, Oncology or appropriate specialist, depending on the indication submitted.
Coverage Duration	Dependent on infection and recommended treatment standards.
Other Requirements & Renewal Information	Requests for off-label use: See PHC criteria document ***Case-by-Case TAR Requirements and Considerations.***

Standard Requirements for Antifungal Agents

(TAR review criteria when drug-specific criteria is not otherwise specified)

Medical Billing:

Medical Billing Requirements, with an approved TAR:
Note that this table may be incomplete. The above criteria apply to all antibacterial products that require a TAR and are without drug-specific criteria.

** TARs and claims must include NDC – add when the HCPCS is J3490, J3590

HCPCS	Description
J0348	Anidulafungin injection, 1 mg (Eraxis™)
J0637	Caspofungin injection, 5 mg (Cancidas™)
J3465	Voriconazole injection, 10 mg (Vfend™)
J1833	Isavuconazonium injection, 1 mg (Cresemba™)
J3049	Injection, rezafungin 200mg vial (Rezzayo™)

Requirements for Chimeric Antigen Receptor T-cell (CAR-T) Therapy

Unless otherwise specified as having renewal requirements, criteria apply to new starts only. Include documentation of continuation of care if member is not new to treatment. Unless otherwise specified, brand names are shown for reference only and the criteria apply to the generic drug ingredient regardless of manufacturer.

PA Criteria	Criteria Details
Covered Uses	Per FDA approved indications included in the product labeling. CAR-T immunotherapy products included in this criteria: • Idecabtagene vicleucel (Abecma™) • Lisocabtagene maraleucel (Breyanzi™) • Ciltacabtagene autoleucel (Carvykti™) • Tisagenlecleucel (Kymriah™) • Brexucabtagene autoleucel (Tecartus™) • Axicabtagene ciloleucel (Yescarta™)
Exclusion Criteria	• CAR-T will not be approved for use as first-line therapy. • Concurrent or prior treatment with another CAR-T immunotherapy. • Concurrent use with a chemotherapy regimen (excluding the necessary lymphodepleting regimen). • CNS disorders or CNS malignancy/metastasis • Active infectious disease. • Inability to remain in the vicinity of the REMS certified facility for a minimum of 4 weeks. • ECOG grade 4 or worse.
Required Medical Information	• Histologically confirmed diagnosis of one of the FDA approved indication for which therapy is being requested to treat. • Testing/analysis confirming CD19 tumor expression (excluding Abecma™ and Carvykti™). • Clinic notes documenting history and course of illness, including response to previous therapies. • Documentation that member does not have active infection, and the recommended screenings in the package labeling, or in treatment guidelines, have been or will be performed for (including but not limited to): Hepatitis B, Hepatitis C, HIV, and TB. • Documentation that member does not have an autoimmune disease or graft-vs-host disease requiring immunosuppression. • Documentation that member will undergo the recommended lymphodepleting regimen prior to CAR-T treatment (cyclophosphamide + fludarabine or appropriate alternative as recommended by package labeling or treatment guidelines). • Documentation that member is able to remain in the vicinity of the certified healthcare facility for at least 4 weeks post-infusion. • Member's current bone marrow, cardiac, pulmonary, liver, and renal function (all organ function must be adequate). • ECOG (Eastern Cooperative Oncology Group) performance status grade. • Policy MCUP3138 External Independent Medical Review will apply, enabling Partnership to obtain a specialist's evaluation of the case prior to both approvals and denials not meeting medical necessity.
Age Restriction	See prescriber information per drug specific approval information. For most indications, CAR-T may be approved for members aged 18 or older. Noted exception for tisagenlecleucel (Kymriah™) when used for the treatment of precursor acute lymphoblastic leukemia which is limited to members aged 25 years and younger on the date of the infusion (date of service), not previously treated with any gene therapy.

Requirements for Chimeric Antigen Receptor T-cell (CAR-T) Therapy

Prescriber Restriction	Prescribed by a hematologist or oncologist
Coverage Duration	A 3 month treatment window on the authorization but limited to 1 dose only per lifetime.
Other Requirements & Information	Additional required information per FDA-approved indication, at time of publication. **Multiple myeloma, relapsed or refractory:** FDA-approved CAR-T therapies with this indication**: Abecma™, Carvykti™.** Additional information required with request: • Documentation of treatment failure (either due to intolerable adverse reaction or lack of efficacy) with at least 4 prior therapies, with at least one from each mechanism of action group listed below included among the prior 4 lines of treatment: a) An anti-CD38 monoclonal antibody: daratumumab (Darzalex), daratumumab-hyaluronidase (Darzalex Faspro), or isatuximab (Sarclisa) b) A proteasome inhibitor: bortezomib (Velcade), carfilzomib (Kyprolis), or ixazomib (Ninlaro) c) An immunomodulatory agent: lenalidomide (Revlimid), thalidomide (Thalomid, accepted off-label use), or pomalidomide (Pomalyst) **Large B-cell lymphoma, relapsed or refractory:** FDA-approved CAR-T therapies with this indication: **Breyanzi™, Kymriah™, Yescarta™.** Additional information required with request: • A confirmed diagnosis of CD19-positive large B-cell lymphoma (by testing or analysis confirming CD19 protein on the surface of the B-cell and documented in the members medical record), including ANY of the following types: ▪ Diffuse large B-cell lymphoma (DLBCL) not otherwise specified (including DLBCL arising from follicular lymphoma or transformed follicular lymphoma-TFL) ▪ Primary mediastinal large B-cell lymphoma ▪ High grade B-cell lymphoma • Documentation of treatment of large B-cell lymphoma in adults that is refractory to first-line chemoimmunotherapy or that relapses within 12 months of first-line chemoimmunotherapy OR • Member has evidence of disease progression after two or more chemotherapy regimens recommended as first or second-line in compendia such as NCCN which may or may not have included therapy supported by allogeneic stem cell transplant. • Limitations of use: Not indicated for treatment of primary CNS lymphoma. **Follicular lymphoma, relapsed or refractory:** FDA-approved CAR-T therapies with this indication: **Kymriah™, Yescarta™.** • Documentation of treatment of relapsed or refractory follicular lymphoma in adults after two or more chemotherapy regimens recommended as first or second line in compendia such as NCCN that includes a combination of an anti-CD20 monoclonal antibody (e.g. rituximab, obinutuzumab) and an alkylating agent (e.g. bendamustine, cyclophosphamide, chlorambucil) **Acute lymphoblastic leukemia (ALL), B-cell precursor, relapsed or refractory:** FDA-approved CAR-T therapies with this indication for children and young adults up to 25 years of age: **Kymriah™**.

Requirements for Chimeric Antigen Receptor T-cell (CAR-T) Therapy

	FDA-approved CAR-T therapies with this indication for adults 18 years and older: **Tecartus™**. • Documentation of treatment of relapsed or refractory B-cell precursor ALL. • Member has a confirmed CD19-positive B-cell precursor ALL (by testing or analysis confirming CD19 protein on the surface of the B-cell and documented in the members medical record) and the members condition meets ONE of the additional criteria, as specified below in either item 1 or item 2: 1. Second or later relapse B-cell precursor ALL after failing at least two lines of adequate treatment (with relapse defined as the reappearance of leukemia cells in the bone marrow or peripheral blood after complete remission with chemotherapy and/or allogeneic cell transplant) OR 2. Refractory B-cell precursor ALL with refractory defined as failure to obtain complete response with induction therapy (with second or later bone marrow relapse, bone marrow relapse after allogeneic stem cell transplant, or primary refractory or chemorefractory after relapse) • Members with Ph+ ALL require documentation of failure of 2 tyrosine kinase inhibitors (e.g., imatinib, dasatinib, nilotinib, bosutinib, ponatinib) at up to maximally indicated doses is required, unless contraindicated or clinically significant adverse effects are experienced, PHC prior authorization may be required for tyrosine kinase inhibitors. **Mantle cell lymphoma, relapsed or refractory:** FDA-approved CAR-T therapies with this indication: **Tecartus™.** • Documentation of treatment of relapsed or refractory mantle cell lymphoma (MCL) in adults. • Documentation of prior treatment with, or intolerance or contraindication to, all of the following: a) Anthracycline or bendamustine containing chemotherapy b) An anti-CD20 antibody (rituximab) c) BTK (bruton tyrosine kinase) inhibitor (acalabrutinib, ibrutinib, zanubrutinib). Requests for off-label use: See PHC criteria document *Case-by-Case TAR Requirements and Considerations.*

Requirements for Chimeric Antigen Receptor T-cell (CAR-T) Therapy

Medical Billing:

Dose limits & billing requirements (approved TAR is required). PHC is following the State's special billing process which divides rate into one fifth the total (or one sixth as is the case with Kymriah™). Treatment at an outpatient hospital/infusion center locations would be billed as 1 service of 5 units (6 units for Kymriah ™) regardless of the # of bags provided by the manufacturer. Total reimbursement will thus be 5 (or 6 for Kymriah™) times the State Medi-Cal rate per units. All are limited to 1 service per lifetime.

Product	**HCPCS**	**HCPCS Description**	**Special Billing Instructions** (mirrors State Medi-Cal instructions due to system limitations on high-dollar drugs which affect how rates are implemented per unit)
Abecma™	Q2055	Idecabtagene vicleucel, up to 460 million autologous b-cell maturation antigen (bcma) directed car-positive t cells, including leukapheresis and dose preparation procedures, per therapeutic dose	Recommended dose: 300 to 460 x 10^6 CAR-T cells, not to exceed the maximum dose of 460 million cells (may be provided in one or more IV bags) **Outpatient hospital billing**: 1 dose is billed as 5 units as above (regardless of the # of bags provided by the manufacturer).
Breyanzi™	Q2054	Lisocabtagene maraleucel, up to 110 million autologous anti-cd19 car-positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose	Recommended dose: 50 to 110 x 10^6 CAR-T cells, not to exceed the maximum dose of 110 million CAR-T cells (may be provided in one or more IV bags). **Outpatient hospital billing**: 1 dose is billed as 5 units as above (regardless of the # of bags provided by the manufacturer).
Carvykti™	Q2056	Ciltacabtagene autoleucel, up to 100 million autologous b-cell maturation antigen (bcma) directed car-positive t cells, including leukapheresis and dose preparation procedures, per therapeutic dose.	Recommended dose: 0.5-1.0 x 10^6 CAR-T cells per kg of body weight, not to exceed the maximum dose of up 100 million CAR-T cells (provided in a single IV bag). **Outpatient hospital billing**: 1 dose is billed as 5 units as above.
Kymriah™	Q2042	Tisagenlecleucel, up to 600 million car-positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose	Recommended dose varies per indication with range: 0.1 to 6 x 10^8 CAR-T cells, not to exceed maximum dose of 600 million CAR-T cells (provided in single IV bag). **Outpatient hospital billing**: 1 dose is billed as 6 units as above.
Tecartus™	Q2053	Brexucabtagene autoleucel, up to 200 million autologous anti-cd19 car positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose	Recommended dose varies per indication with range: 1 to 2 x 10^6 CAR-T cells, not to exceed maximum dose of 200 million CAR-T cells (provided in single IV bag). **Outpatient hospital billing**: 1 dose is billed as 5 units as above.
Yescarta™	Q2041	Axicabtagene ciloleucel, up to 200 million autologous anti-cd19 car positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose	Recommended dose: 2 x 10^6 CAR-T cells, not to exceed maximum dose of 200 million CAR-T cells (provided in single IV bag). **Outpatient hospital billing**: 1 dose is billed as 5 units as above.

Requirements for Leuprolide mesylate (Camcevi™)

Unless otherwise specified as having renewal requirements, criteria apply to new starts only. Include documentation of continuation of care if member is not new to treatment. Unless otherwise specified, brand names are shown for reference only and the criteria apply to the generic drug ingredient regardless of manufacturer or labeler.

PA Criteria	Criteria Details
Covered Uses	Treatment of adult patients with advanced prostate cancer
Exclusion Criteria	None
Required Medical Information	1) Oncology notes documenting diagnosis, stage and current and prior treatments 2) Documentation of trial and failure or reasons why Lupron Depot or Eligard cannot be used
Age Restriction	≥18
Prescriber Restriction	Must be prescribed or recommended by an oncologist
Coverage Duration	12 months
Other Requirements & Information	Requests for off-label use: See PHC criteria document *Case-by-Case TAR Requirements and Considerations.*

Medical Billing:

Dose limits & billing requirements, with an approved TAR:

HCPCS	Description	Dosing, Units
J1952	Leuprolide injectable, camcevi, 1 mg (Camcevi™)	42mg every 6 months (42 units every 6 months, or 84 units annually)

Requirements for posaconazole IV (Noxafil™)

Unless otherwise specified as having renewal requirements, criteria apply to new starts only. Include documentation of continuation of care if member is not new to treatment. Unless otherwise specified, brand names are shown for reference only and the criteria apply to the generic drug ingredient regardless of manufacturer or labeler.

PA Criteria	Criteria Details
Covered Uses	• Treatment of invasive aspergillosis • Prophylaxis of invasive *Aspergillus* and *Candida* infections in patients who are at high risk of developing these infections due to being severely immunocompromised, such as hematopoietic stem cell transplant (HSCT) recipients with graft versus-host disease (GVHD) or those with hematologic malignancies with prolonged neutropenia from chemotherapy
Exclusion Criteria	None
Required Medical Information	1) Clinic notes and relevant imaging and laboratory results to confirm primary and secondary diagnoses, treatment history, and current treatment plan with anticipated duration of therapy 2) Documentation of trial and failure or reasons why other treatment options cannot be used. Preferred, first-line treatment options may include the following: amphotericin B, anidulafungin, caspofungin, micafungin, fluconazole, itraconazole, voriconazole (TAR may be required for other treatment options.) 3) Documentation to confirm NPO status, unable to take tablets/capsules or oral suspension
Age Restriction	≥13 years for treatment ≥ 2 years for prophylaxis
Prescriber Restriction	Prescribed or recommended by Infectious Disease specialist or HIV specialist
Coverage Duration	TBD based on indication
Other Requirements & Information	Requests for off-label use: See PHC criteria document *Case-by-Case TAR Requirements and Considerations.*

Medical Billing:

Dose limits & billing requirements, with an approved TAR:

HCPCS	Description	Dosing, Units
J3490	Unclassified Drug (NDC billing): Posaconazole300 mg/16.7 ml single dose vial (Noxafil).	PHC NDC billing/reimbursement is by each: 1 unit=1 vial 300mg BID for 1 day, then 300mg daily thereafter for 6-12 weeks (treatment) or based upon recovery from neutropenia or immunosuppression (prophylaxis)

Requirements for Tedizolid (Sivextro™), Oritavancin (Orbactiv™), and Dalbavancin (Dalvance™)

Unless otherwise specified as having renewal requirements, criteria apply to new starts only. Include documentation of continuation of care if member is not new to treatment. Unless otherwise specified, brand names are shown for reference only and the criteria apply to the generic drug ingredient regardless of manufacturer or labeler.

PA Criteria	Criteria Details
Covered Uses	For Acute bacterial skin and skin structure infections (ABSSI) caused by susceptible isolates of gram positive organisms: S. aureus (methicillin susceptible & resistant), S. pyogenes, S. agalactiae, S. dysgalactiae, S. anginosis, E. faecalis (vancomycin susceptible only for oritavancin, VRE for tedizolid).
Exclusion Criteria	None
Required Medical Information	• Culture and sensitivity report showing susceptible isolate • Applicable labs and/or tests documenting antibiotic selection. • Relevant clinical notes such as hospital discharge. • Summary or infectious disease consult notes • Documentation of trial and failure/contraindication to vancomycin or alternative antibiotic that organism is susceptible to, may include, but not limited to: TMP/SMX, doxycycline, dicloxacillin, cephalexin, daptomycin, nafcillin, cefazolin, clindamycin, linezolid
Age Restriction	Sivextro: ≥12 years Orbactiv: ≥18 years Dalvance: none
Prescriber Restriction	None
Coverage Duration	One treatment course Sivextro: 6 days Orbactiv: one-time single dose (1200mg) Dalvance: 1 weeks (2 doses, 1 week apart, total 1500mg)
Other Requirements & Information	Requests for off-label use: See PHC criteria document *Case-by-Case TAR Requirements and Considerations.*

Requirements for Tedizolid (Sivextro™), Oritavancin (Orbactiv™), and Dalbavancin (Dalvance™)

Medical Billing:

Dose limits & billing requirements, with an approved TAR:

Product	HCPCS	Description	Dosing, Units
Sivextro	J3090	Injection, tedizolid phosphate, 1 mg	200mg (200 units) daily for 6 days, maximum of 1200 units per course
Orbactiv	J2407	Injection, oritavancin (orbactiv), 10 mg	1200mg (120 units) one time per treatment course
Dalvance	J0875	Injection, dalbavancin, 5 mg	