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 Partnership HealthPlan of California Policy #MPRP4033.

Depemokimab (Exdensur™)	Mepolizumab (Nucala™)	Tezepelumab (Tezspire™)
Tedizolid (Sivextro™)	Oritavancin (Orbactiv™)	Zopapogene Imadenovec (Papzimeos™)
Daptomycin (Xelia™)	Posaconazole IV (Noxafil™)	Immunoglobulin (Human) Products (IVIG, IMIG, SCIG™)

Requirements for Depemokimab (Exdensur™ AutoInjector Pen & Exdensur™ Prefilled Syringe)

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	Add-on maintenance treatment of severe asthma in adults and pediatric patients ≥12 years of age with an eosinophilic phenotype
Exclusion Criteria	• Monotherapy use (depemokimab is add on therapy to the current asthma treatment regimen) • Depemokimab will not be used concurrently with other monoclonal antibodies with similar indications such as dupilumab, benralizumab, mepolizumab, omalizumab, reslizumab or Tezepelumab
Required Medical Information	Clinic notes must include all the following: 1) Member has a diagnosis of severe asthma with an eosinophilic phenotype and has a blood eosinophil count equal to or greater than 150 cells/μL at screening or history of blood eosinophils ≥300 cells/μL within the last year 2) Member is adherent on medium or high-dose inhaled corticosteroids (ICS) and at least one additional asthma controller (such as long acting beta2 agonist (LABA), with or without oral corticosteroids (OCS) for at least 3 months 3) Member has persistent uncontrolled asthma as defined by at least one of the following: a. An Asthma Control Questionnaire (ACQ6) score of 1.5 or more, or an Asthma Control Test (ACT) score less than 20 at baseline b. A history of at least two asthma exacerbation events within prior 12 months c. A history of at least one severe asthma exacerbation resulting in hospitalization within prior 12 months d. Reduced lung function at baseline [pre-bronchodilator FEV1 below 80% in adults, and below 90% in adolescents] e. Member has inadequate asthma control (for example, hospitalization or emergency medical care visit within the past year) despite current treatment with both of the following medications at optimal dosages: i. Inhaled corticosteroid; and ii. Long acting beta2-agonist, leukotriene modifier, or sustained release theophylline)
Age Restriction	12 years of age or older
Prescriber Restriction	Prescribed by, or in consultation with an allergist, immunologist, or pulmonologist
Coverage Duration	Initial approval: 6 months Renewal: 12 months with documentation of clinical benefit with treatment when compared to baseline (see further details in "Other Criteria" section below)
Other Requirements & Information	<u>Renewal criteria:</u> 1) Current FEV1, peak flow and/or other pulmonary function test that may indicate improvement in airflow limitations 2) Asthma Control Questionnaire (ACQ6) or Asthma Control Test (ACT) after a minimum of 3 months after initiation of treatment with depemokimab to indicate improvement from baseline score

Requirements for Depemokimab (Exdensur™ AutoInjector Pen & Exdensur™ Prefilled Syringe)

	Note: Pharmacy claim history will be reviewed for renewal requests, and rescue inhalers should not show increasing use. If the fill history does show an increase in use for rescue inhalers, then additional justification of depemokimab efficacy may be requested. 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
J3590	Unclassified biologics: depemokimab (Exdensur)	Asthma • ≥12 years • 100 mg once every 6 months.

Requirements for Mepolizumab (Nucala™ Autoinjector Pen, Nucala™ Prefilled Syringe, & Nucala™ vials)

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) Add-on maintenance treatment of severe asthma in adults with an eosinophilic phenotype. 2) Eosinophilic granulomatosis with polyangiitis (Churg-Strauss Syndrome or EGPA). 3) Hypereosinophilic syndrome (HES) for ≥ 6 months without an identifiable non-hematologic secondary cause. 4) Add-on maintenance treatment of chronic rhinosinusitis with nasal polyps (CRSwNP) with inadequate response to nasal corticosteroids. 5) Add-on maintenance treatment of chronic obstructive pulmonary disease (COPD) in adults who are inadequately controlled and have an eosinophilic phenotype.
Exclusion Criteria	• When used as monotherapy (mepolizumab is add on therapy to the current asthma and/or COPD treatment regimen) • When used concurrently with other monoclonal antibodies with similar indications such as benralizumab, dupilumab, omalizumab, reslizumab or tezepelumab • When used concurrently with ensifentrine for COPD
Required Medical Information	TARs must include the NDC &/or the stated dosage form that is being requested for administration during the medical visit (Pens *vs* Syringes *vs* Vials): • Nucala™ Autoinjector pen or prefilled syringes: FDA approved for self or caregiver administration with proper training. • Nucala™ Vials: FDA approved for administration by health care provider. Asthma: documentation that demonstrates all the following: 1) Member has asthma with an eosinophilic phenotype defined as blood eosinophils greater than or equal to 300 cells/µL within previous 12 months or greater than or equal to 150 cells/µL within six weeks of dosing and 2) Member has inadequate asthma control (for example, hospitalization or emergency medical care visit within the past year) despite current treatment with both of the following medications at optimal dosages a. Inhaled corticosteroid; and b. Long acting beta2-agonist, leukotriene modifier, or sustained release theophylline) EGPA: documentation that demonstrates all the following: 1) Member has a history or the presence of an eosinophil count of more than 1000 cells/µL or a blood eosinophil level of higher than 10 percent 2) Member has two or more of the following disease characteristics of EGPA: a. Biopsy showing histopathological evidence of eosinophilic vasculitis, perivascular eosinophilic infiltration, or eosinophil-rich granulomatous inflammation b. Neuropathy c. Pulmonary infiltrates d. Sinonasal abnormalities e. Cardiomyopathy f. Glomerulonephritis g. Alveolar hemorrhage h. Palpable purpura i. Antineutrophil Cytoplasmic Antibody (ANCA) positivity 3) Member has had at least one relapse (requiring increase in oral corticosteroids dose, initiation/increased dose of immunosuppressive therapy or

Requirements for Mepolizumab (Nucala™ Autoinjector Pen, Nucala™ Prefilled Syringe, & Nucala™ vials)

	hospitalization) within 2 years prior to starting treatment with Nucala or has a refractory disease. CRSwNP: documentation that demonstrates all the following: 1) History of prior nasal polyp removal surgery along with date of procedure. 2) Treatment failure with ≥ 8 weeks of a nasal corticosteroid 3) Recurrent and symptomatic CRSwNP (e.g. loss of smell/taste, nasal obstruction, rhinorrhea, facial pressure) indicated by: a. Visual analogue scale (VAS) score > 5 (access total clinical symptoms) AND b. Bilateral nasal polyp score (NPS) ≥ 5 or NPS ≥ 2 for a single nasal cavity (extent/severity of polyps based on endoscopic evaluation). HES: documentation that demonstrates all the following: 1) Clinic notes to confirmation the diagnosis of HES ≥ 6 months 2) Clinic notes to indicate that secondary potential causes of non-hematologic eosinophilia have been ruled out, such as but not limited to: a. FIP1L1-PDGFRα kinase positive b. Parasitic helminth infection c. Drug hypersensitivity d. HIV infection e. Non-hematologic malignancy 3) Signs and symptoms of organ involvement 4) At least 2 HES flares within the past 12 months 5) Current lab report with absolute eosinophil count (AEC) ≥1,500 cells/uL 6) Documentation of failure to induce remission with a corticosteroid (first line therapy) 7) Documentation of failure to induce remission with hydroxyurea or imatinib (Gleevec™) COPD: documentation that demonstrates all the following: 1) Member has COPD with both: a. postbronchodilator FEV1/FVC <0.7 on spirometry and b. BEC ≥150 cells/µL at screening or ≥300 cells/µL in the previous 12 months 2) Member has inadequate COPD control (for example, history of ≥2 moderate or ≥1 severe COPD exacerbations within the last year) despite current treatment with all 3 of the following medications at optimal dosages a. inhaled LABA b. LAMA c. ICS triple therapy • *COPD exacerbations are defined as:* ○ *Moderate: worsening of COPD symptoms that required treatment with systemic corticosteroids (oral or intravenous) and/or antibiotics.* ○ *Severe: an event that required an in-patient hospitalization (lasting at least 24 hours).*
Age Restriction	Asthma: 6 yrs and older EGPA: 18 yrs and older HES: 12 yrs and older CRSwNP: 18 yrs and older COPD: 18 yrs and older
Prescriber Restriction	None

Requirements for Mepolizumab (Nucala™ Autoinjector Pen, Nucala™ Prefilled Syringe, & Nucala™ vials)

Coverage Duration	Vials: 1 dose to allow administration of starting dose with the goal of transitioning to the autoinjector pen or prefilled syringe for maintenance treatment at home (provided by the pharmacy). Autoinjector pens & Prefilled syringes 1 time dose for training & observation of self-administration technique.
Other Requirements & Information	Mepolizumab (Nucala™) is available for self-administration in the form of an autoinjector and a prefilled syringe, which are typically administered by the member or a caregiver at home. When the member or caregiver can be trained for self-administration, Nucala™ autoinjector or prefilled syringes should be provided to the member by a pharmacy for administration at home whenever possible. Vials: Requests will be approved up to 1 month, if the healthcare provider prefers to administer the first dose for new start requests, by obtaining it through the practice until safety is determined. Autoinjector Pen & Prefilled syringes: Requests will be approved for one-time to allow training of the member &/or caregiver on self-administration. Continuing to provide an autoinjector pen or pens through the medical office will require information submitted with the TAR documenting the member is not a candidate for self- or caregiver administration at home. If administration by the provider is requested beyond the time frames shown above, the provider must include reason(s) on the renewal TAR stating why the member or caregiver cannot obtain the drug through the pharmacy benefit for self- or caregiver administration.

Medical Billing:

Dose limits & billing requirements (approved TAR is required):

J2182	Injection, mepolizumab, per 1 mg (Nucala™ Autoinjector Pen & Prefilled syringe)	Asthma • 12 yrs and older: 100 mg (100 units) subcutaneously (SC) every 4 weeks • 6-11 yrs: 40 mg (40 units) SC every 4 weeks
		EGPA • 18 yrs and older: 300 mg (300 units) SC every 4 weeks
		HES • 18 yrs and older: 300 mg (300 units) SC every 4 weeks
		CRSwNP • 18 yrs and older: 100 mg (100 units) SC every 4 weeks
		COPD • 18 yrs and older: 100 mg (100 units) SC every 4 weeks
		Maximum Dose: 300 mg (300 HCPCS units per service date)

Requirements for Tezepelumab
(Tezspire™ Autoinjector Pen & Prefilled Syringes)

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) Add-on maintenance treatment of severe asthma. 2) Add-on maintenance treatment of chronic rhinosinusitis with nasal polyps (CRSwNP) with inadequate response to nasal corticosteroids.
Exclusion Criteria	• Monotherapy use (tezepelumab is add-on therapy to the current asthma treatment regimen) • Tezepelumab will not be used concurrently with other monoclonal antibodies with similar indications such as dupilumab, mepolizumab, omalizumab, reslizumab or benralizumab
Required Medical Information	TARs must include clinical documentation to substantiate the following: Asthma: 1) Patient has a physician-diagnosed asthma for at least 12 months 2) Patient is adherent on medium or high-dose inhaled corticosteroids (ICS) and at least one additional asthma controller (such as long acting beta2 agonist (LABA), with or without oral corticosteroids (OCS) 3) Patient has persistent uncontrolled asthma as defined by at least one of the following: a. An Asthma Control Questionnaire (ACQ6) score of 1.5 or more, or an Asthma Control Test (ACT) score less than 20 at baseline b. A history of at least two asthma exacerbation events within prior 12 months c. A history of at least one severe asthma exacerbation resulting in hospitalization within prior 12 months d. Patient has inadequate asthma control (for example, hospitalization or emergency medical care visit within the past year) despite current treatment with both of the following medications at optimal dosages: i. Inhaled corticosteroid; and ii. Long acting beta2-agonist, leukotriene modifier, or sustained release theophylline). 4) State the specific dosage form that will be administered during the medical office visit: a. Tezspire™ Autoinjector pen (may be administered by patient or caregiver with proper training) OR Tezspire™ Prefilled Syringe (administered by health care provider) CRSwNP: 1) History of prior nasal polyp removal surgery along with date of procedure. 2) Treatment failure with ≥ 8 weeks of a nasal corticosteroid 3) Recurrent and symptomatic CRSwNP (e.g. loss of smell/taste, nasal obstruction, rhinorrhea, facial pressure) indicated by: • Visual analogue scale (VAS) score > 5 (access total clinical symptoms) AND • Bilateral nasal polyp score (NPS) ≥ 5 or NPS ≥ 2 for a single nasal cavity (extent/severity of polyps based on endoscopic evaluation).
Age Restriction	Asthma: 12 yrs and older

Requirements for Tezepelumab (Tezspire™ Autoinjector Pen & Prefilled Syringes)

	CRSwNP: 18 yrs and older
Prescriber Restriction	Must be prescribed by or in consultation with a pulmonologist, allergist or immunologist
Coverage Duration	Prefilled syringes: 1 dose to allow administration of starting dose with the goal of transitioning to the autoinjector or prefilled syringe for maintenance treatment at home (provided by the pharmacy). Autoinjector pens: 1 time dose for training & observation of self-administration technique
Other Requirements	Tezepelumab (Tezspire™) is available for self-administration in the form of an autoinjector pen, which are typically administered by the member or a caregiver at home. The member or caregiver can be trained for self-administration, Tezspire™ autoinjector pen should be provided to the member by a pharmacy for administration at home whenever possible. Prefilled syringes: Requests will be approved for one-time, if the healthcare provider prefers to administer the first dose for new start requests, by obtaining it though the practice. Autoinjector pens: Requests will be approved for one-time to allow training of the member &/or caregiver on self-administration. Continuing to provide auto-injector pens through the medical office will require information submitted with the TAR documenting the member is not a candidate for self- or caregiver administration at home. If administration by the provider is requested beyond the time frames shown above, the provider must include reason(s) on the renewal TAR stating why the member or caregiver cannot obtain the drug through the pharmacy benefit for self- or caregiver administration.

Medical Billing:

Dose limits & billing requirements (approved TAR is required):

HCPCS	Description	Dosing, Units
J2356	Injection, tezepelumab-ekko, 1 mg (Tezspire™ auto-injector pen & Tezspire™ prefilled syringe)	• Recommended (& maximum) dose: 210 mg Asthma: • 12 yrs and older: 210 mg (210 units) subcutaneously (SC) once every 4 weeks CRSwNP: • 18 yrs and older: 210 mg (210 units) SC every 4 weeks
		1 HCPCS unit = 1 mg, therefore a 210 mg dose is billed as a count of 210 units of service.

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

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, oral tedizolid • Sivextro: current weight (must be ≥1kg)
Age Restriction	Sivextro: ≥26 weeks gestational age Orbactiv: ≥18 years
Prescriber Restriction	None
Coverage Duration	One treatment course Sivextro: 6 days Orbactiv: one-time single dose (1200mg)
Other Requirements & Information	Requests for off-label use: See PHC criteria document *Case-by-Case TAR Requirements and Considerations.*

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

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

Requirements for Zopapogene Imadenovec (Papzimeos™)

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	The treatment of recurrent respiratory papillomatosis (RRP)
Exclusion Criteria	1. RRP caused by HPV subtype other than 6 or 11 2. Active, significant, autoimmune disease 3. Ongoing use of systemic corticosteroids at a dose of ≥10mg of prednisone equivalents, or other systemic immunosuppressive medications
Required Medical Information	<u>Documentation of ALL of the following (1-10):</u> 1. Clinic notes which include past medical history of RRP including disease progression and the number and dates of all surgical interventions performed within the previous 12 months 2. Member has current symptoms of RRP disease such as airway compromise, voice impairment or dysphagia (such as a copy of the Derkay Severity Score) 3. Presence of laryngotracheal papillomas via endoscopy 4. Histological diagnosis of papilloma confirmed by pathology report from a CLIA-certified (or comparable) laboratory 5. Confirmation of HPV subtype 6 or 11 6. Documentation that member has received Gardasil-9 if they are between the ages of 9-45 years old, or reasons why the Gardasil-9 vaccine cannot be administered. Vaccination with Gardasil-9 should be strongly considered for members over the age of 45 as well. 7. Baseline Derkay Severity Score based on endoscopic findings 8. Member must meet ONE of the following: a. Has received ≥3 clinically indicated surgical interventions in the previous 12 months, OR b. Severe disease burden (Derkay score ≥20 for anatomic score), OR c. Tracheobronchial or pulmonary disease, OR d. Rapid regrowth after surgery (disease requiring repeat surgical intervention within 8–12 weeks of prior debulking), OR e. Need for tracheostomy or long term ventilatory support due to disease burden 9. Confirmation that the member will receive surgical debulking to maintain minimal residual disease prior to the first dose, and again prior to the 3rd and 4th doses if indicated 10. Member has no severe uncontrolled medical illness 11. Member has no active infection 12. Negative pregnancy test 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
Age Restriction	18 years and older
Prescriber Restriction	Otolaryngologist

Requirements for Zopapogene Imadenovec (Papzimeos™)

Coverage Duration	One treatment course per authorization: 4 doses over 12 weeks
Other Requirements & Information	Renewal Requirements: ALL of the following (1-3) 1. ≥12 months have elapsed since completion of the prior Papzimeos course 2. Documentation of a positive response to prior Papzimeos, such as ONE of the following: a. Reduction in surgical frequency compared to baseline b. Reduction in Derkay score compared to baseline 3. Documentation of disease recurrence after favorable response, such as ONE of the following: a. Increasing Derkay score b. Increasing surgical frequency c. Symptomatic recurrence Requests for off-label use: See Partnership criteria document *Case-by-Case TAR Requirements and Considerations.*

Medical Billing:

Dose limits & billing requirements, with an approved TAR:

J3404	Injection, zopapogene imadenovec-drba suspension, per therapeutic dose	5×10^{11} particle units (PU) per injection administered as subcutaneous injections given on day 0, and repeated on week 2, week 6 and week 12 for a total of 4 doses. Approvals should be for 4 units total

Requirements for Non-Preferred Daptomycin Products: J0872

(preferred Daptomycin products do not require a TAR)

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	<u>All Diagnoses</u>: 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: a. Doxycycline b. Minocycline c. SMZ/TPM (Septra DS) d. Erythromycin e. Penicillins f. Cephalosporins g. Linezolid 2) Trial and failure or medical reasons why preferred daptomycin products cannot be used (preferred daptomycin products do not require a TAR and can be billed with HCPCS codes: J0878, J0877, J0874 and J0873) <u>MRSA (either cSSSI or bacteremia)</u> 1) IV treatment must be indicated 2) Documentation of failure, or reasons why vancomycin cannot be used 3) An Infectious Disease consult may be required 4) Trial and failure or medical reasons why preferred daptomycin products cannot be used (preferred daptomycin products do not require a TAR and can be billed with HCPCS codes: J0878, J0877, J0874 and J0873)
Age Restriction	≥ 1 year
Prescriber Restriction	None

Requirements for Non-Preferred Daptomycin Products: J0872

(preferred Daptomycin products do not require a TAR)

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.*

Medical Billing:

Dose limits & billing requirements, with an approved TAR:

Product	HCPCS	Description	Dosing, Units
Daptomycin	J0872	Injection, daptomycin (xellia), unrefrigerated, not therapeutically equivalent to J0878 or J0873, 1 mg	Weight based dosing, administered once every 24 hours

Age	cSSSI (7-14 days)	Bacteremia (2-6 weeks)
>17 yrs	4mg/kg	6mg/kg
12-17 yrs	5mg/kg	7mg/kg
7-11 yrs	7mg/kg	9mg/kg
2-6 yrs	9mg/kg	12mg/kg
1-<2 yrs	10mg/kg	

Note: the following daptomycin products do not require a TAR:
J0878: Injection, daptomycin, 1 mg (Cubicin™)
J0877: Injection, daptomycin (hospira), not therapeutically equivalent to J0878, 1 mg
J0874: Injection, daptomycin (baxter), not therapeutically equivalent to J0878, 1 mg
J0873: Injection, daptomycin (xellia), not therapeutically equivalent to j0878 or j0872, 1 mg

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 4) Current weight (must be ≥10kg)
Age Restriction	≥ 2 years and older
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
J1837	Injection, posaconazole, 1 mg (Noxafil)	Adults: 300mg BID for 1 day, then 300mg daily thereafter for 6-12 weeks (treatment) or based upon recovery from neutropenia or immunosuppression (prophylaxis) Pediatric: 6mg/kg up to a maximum of 300mg BID for 1 day, then 6mg/kg up to a maximum of 300mg daily thereafter for 6-12 weeks (treatment) or based upon recovery from neutropenia or immunosuppression (prophylaxis)

Requirements for Immunoglobulin (Human) Products (IVIG, IMIG, SCIG)

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: • Antiviral Prophylaxis • Chronic Inflammatory Demyelinating Polyneuropathy • Dermatomyositis/Polymyositis, Severe, Life Threatening or Refractory • Hypogammaglobinemia, prophylaxis against bacterial infection with hypogammaglobinemia and/or recurrent bacterial infections with malignancy or primary humoral immunodeficiency disorder (PI/PID) or Common variable immunodeficiency (CVID) • Acute and Chronic Immune Thrombocytopenia (ITP) • Kawasaki Syndrome • Multifocal Motor Neuropathy 2) Medically accepted off-label indications as evidenced in compendia or treatment guidelines, such as but not limited to: • Pemphigus foliaceus and vulgaris, refractory • Toxic shock syndrome, streptococcal • Antibody mediated rejection, treatment • Guillain-Barre syndrome • Acute exacerbation of myasthenia gravis Please note the following are preferred IVIG products with Partnership HealthPlan: Gammagard, Gammaplex, Gamunex-C, Octagam, Privigen, Flebogamma, Bivigam Non-preferred IVIG options: Asceniv, Alyglo, Panzyga, Yimmugo
Exclusion Criteria	None

Required Medical Information	<u>Requirements for ALL indications</u>: (1) Clinic notes to confirm the diagnosis submitted (see specific requirements below). (2) Treatment plan from appropriate specialist, including: • Weight (kg, lb) • Dosing schedule • Previous treatments with other indicated therapies (if any), with evaluation of response. (3) If requesting use of Asceniv, Alyglo, Panzyga, or Yimmugo, please submit additional information regarding reason(s) why alternative products cannot be used. <u>Additional Diagnosis-Dependent Requirements:</u> 1) <u>Antiviral prophylaxis:</u> a. Hepatitis A –pre or post-exposure within 2 weeks for patients who are: • Immunocompromised • Chronic liver disease • Ages ≥ 12 months who are unvaccinated • High-risk exposure situations within a facility (e.g. school, hospital), international travel, or during pregnancy. b. Measles – post exposure within 6 days of exposure and unable to receive a MMR vaccine within 72 hours for patients who meet one of the following parameters: • Infants < 12 months

- Pregnant women or persons without evidence of immunity (rapid IgG antibody test is acceptable).
- Severely Immunocompromised (e.g. bone marrow transplant procedure <12 months after finishing immunosuppressive therapy, graft vs host disease, HIV/AIDs with so CD4 <15% or CD4 <200 lymphocytes/mm3 for ages >5 yrs).

c. Varicella – post exposure, if varicella-zoster immune globulin, such as Varizig is unavailable for:
- Persons without evidence of immunity

2) Chronic inflammatory demyelinating polyneuropathy:
a. Confirmation of diagnosis based on the European Academy of Neurology (EAN/PNS) guidelines
b. Electro diagnostic findings of peripheral nerve demyelination
c. Exclusion of other similar disease states that overlap with similar symptoms, such as but not limited to:
- Neuropathy probably caused by B. burgdorferi infection (Lyme disease), diphtheria, drug or toxin exposure
- Hereditary demyelinating neuropathy
- Prominent sphincter disturbance
- Diagnosis of multifocal motor neuropathy (MMN)
- IgM monoclonal gammopathy with high titer antibodies to myelin-associated glycoprotein (MAG)
- Other causes for a demyelinating neuropathy including POEMS syndrome, osteosclerotic myeloma, and diabetic and nondiabetic lumbosacral radiculoplexus neuropathy; peripheral nervous system lymphoma and amyloidosis may occasionally have demyelinating features

d. Inflammatory Neuropathy Cause and Treatment (INCAT) score, Inflammatory Rasch-built Overall Disability Scale (I-RODS) or similar measurement of impairment
e. Documentation of failure to respond to glucocorticoids (oral or injectable) or reason(s) why glucocorticoids cannot be used such as but not limited to:
- Contraindication
- Severe disability
- Pure motor phenotype
- Fast progressive disease

3) Dermatomyositis/Polymyositis, severe, life-threatening or refractory:
a. Confirmation of diagnosis with at least one of the following:
i. Cutaneous manifestations (e.g. Heliotrope, Gottron's sign, erythema on extremity joints)
ii. Muscle biopsy
iii. Skin biopsy
iv. Electrocardiogram
v. European League Against Rheumatism/American College of Rheumatology (EULAR/ACR) criteria or Bohan and Peter criteria AND

b. Confirmation of diagnosis with at least 4 of the following:
i. Symmetrical muscle weakness in the shoulders/upper arms or hips/upper legs and trunk
ii. Elevation of serum levels of skeletal muscle-associated enzymes: CK, aldolase, lactate dehydrogenase (LD or LDH), transaminases (ALT/SGPT and AST/SGOT)
iii. Muscle pain on grasping or spontaneous pain
iv. The triad of muscle-related changes on EMG:

- Short, small, low-amplitude poly-phasic motor unit potentials
- Fibrillation potentials, even at rest
- Bizarre high-frequency repetitive discharges

v. Positive for any of the myositis-specific autoantibodies
vi. Nondestructive arthritis or arthralgia
vii. Signs of systemic inflammation
viii. Muscle biopsy findings compatible with inflammatory myositis

c. Documentation of failure to respond to or contraindicated to:
   i. Glucocorticoids after an appropriate trial (≥ 3 months)
   ii. Glucocorticoids plus methotrexate or azathioprine after an appropriate trial AND
   iii. Rituximab (Rituxan™)

4) Hypogammaglobulinemia, prophylaxis against bacterial infection:
   a. Documentation to confirm:
      i. Decrease of IgG (at least 2 SD below the mean for age)
      ii. Decrease in at least one of the isotypes IgM or IgA
      iii. Onset of immunodeficiency ≥ 4 years of age
      iv. Absent isohemagglutinins (A and B blood group antigens) and/or poor response to vaccines
      v. History of recurrent bacterial and/or viral infections
      vi. Other causes of hypogammaglobulinemia have been excluded
   b. Treatment plan with anticipated:
      i. Dose
      ii. Frequency
      iii. Transition to subcutaneous treatment, if started treatment with intravenous administration

5) Acute and Chronic Immune thrombocytopenia (ITP):
   a. Clinic notes must confirm low platelet count is due to ITP vs other causes such as malignancy or bone marrow failure, AND
   b. One or more of the following:
      i. Documentation of inadequate response to treatment course with an oral glucocorticoid (dexamethasone, or prednisone), contraindication or intolerance OR
      ii. Severe bleeding symptoms OR
      iii. Planned surgery or invasive procedure OR
      iv. Platelets count between 30,000/microL-50,000/microL in patients ≥18 yrs with one additional high risk factor for bleeding (i.e. peptic ulcer, use of anticoagulants, high risk of falling or chronic Hep. C associated thrombocytopenia OR
      v. Current lab report showing platelet count <30,000/microL, for ages <18 yrs OR <20,000/microL, for ages ≥18 yrs:
         - With at least one risk factor, such as but not limited to:
            - Use of antiplatelet medication or anticoagulation medication
            - Bleeding disorder (e.g. von Willebrand disease)
            - Active lifestyle subject to frequent trauma
            - Close monitoring or medical care is limited
            - Urgent surgery
            - Head trauma

6) Kawasaki syndrome:
   a. Age ≤5 years
   b. Fever of unknown origin or cause ≥ 5 days
   c. Lab report with:
      i. C-reactive protein (CRP)test < 3 mg/dL AND Erythrocyte sedimentation rate (ESR) <40 mm/hr OR

ii. CRP ≥3 mg/dL AND/OR ESR ≥40 mm/hr

d. Positive echocardiogram:
   i. Z-score of the left anterior descending coronary artery or right coronary artery is ≥2.5, a coronary artery aneurysm is observed OR
   ii. ≥3 other suggestive features exist including decreased left ventricular function, mitral regurgitation, pericardial effusion OR
   iii. Z-scores in the left anterior descending coronary artery or right coronary artery of 2 to 2.5.

7) Multifocal motor neuropathy (MMN):
   a. Confirmation of diagnosis based on the European Academy of Neurology (EAN/PNS) guidelines
   b. Exclusion criteria are the following:
      - Upper motor neuron signs
      - Marked bulbar involvement
      - Sensory impairment more marked than minor vibration loss in the lower limbs
      - Diffuse symmetric weakness during the initial weeks
   c. Rasch disability scale for MMN (MMN-RODS(C)) prior to treatment.

Accepted Off-Label use with high level of evidence and/or used in current standards and practices:

8) Guillain-Barre syndrome (GBS):
   a. Clinic notes documenting confirmation of diagnosis, such as but not limited to:
      - Loss of deep tendon reflexes
      - Symmetrical weakness
      - Pain, numbness, tingling in feet
      - Cerebrospinal fluid analysis (more protein observed and few WBC)
      - Electrodiagnostic studies to indicate abnormalities consistent with GBS
      - Dysautonomia
   b. GBS disability score between 3-5 or rapid progression

9) Antibody mediated rejection (AMR), heart, kidney or lung transplant treatment:
   a. See criteria above, listed in the section "Requirements for all indications"

10) Pemphigus foliaceus and vulgaris, refractory:
   a. Documentation of failure to both (i and ii):
      i. Glucocorticoids with an immunosuppressant (i.e. azithromycin, mycophenolate, cyclophosphamide, dapsone, methotrexate).
      ii. Glucocorticoids with rituximab

11) Toxic Shock Syndrome, streptococcal:
   a. Documentation indicating complications associated with toxic shock syndrome due to invasive group A streptococcus pyogenes (GAS) streptococcal toxic shock syndrome.

12) Myasthenia gravis (acute exacerbation):
   a. Documentation indicating treatment required for:
      i. Myasthenia gravis crisis
      ii. Preoperatively
      iii. Bridge therapy while transitioning to slower onset corticosteroid

Requirements for Immunoglobulin (Human) Products (IVIG, IMIG, SCIG)

	sparing immunotherapy
Age Restriction	Per FDA package labeling for each product
Prescriber Restriction	Prescribed by an appropriate specialist (disease state under treatment is within the standard scope of the specialty), or by a PCP with appropriate specialist's consultations & recommendation.
Coverage Duration	Dependent upon the indication submitted
Other Requirements & Information Needed for Continuation of Care	Requests for off-label use: See PHC criteria document *Case-by-Case TAR Requirements and Considerations.* 1) CIDP: a. Inflammatory Neuropathy Cause and Treatment (INCAT) score, Inflammatory Rasch-built Overall Disability Scale (I-RODS) or similar measurement of impairment. i. If symptoms do not improve or continue to progress after an initial two-to-three-month treatment trial, the patient should be reevaluated to verify the diagnosis of CIDP. 2) Hypogammaglobulinemia, prophylaxis against bacterial infection: a. Treatment plan, including expected timeframe for transition from intravenous (IV) to subcutaneous (SC). b. If IV route is to be ongoing without transition to SC, please provide the reason(s) why SC formulations cannot be used. 3) MMN: a. Current Rasch disability scale for MMN (MMN-RODS(C)) prior to renewal request. <u>ITP Renewals</u>: Standard is usually 1-2 treatments, and if no response, alternatives should be considered. Documentation of ongoing moderate or severe bleeding symptoms with persistent platelet count <20,000/microL is required for consideration of additional treatment with IgG. <u>Guillain-Barré Renewals</u>: Limited to a single treatment (standard of care) except when extenuating circumstances are submitted which indicate an additional treatment is medically necessary. Requesting a second treatment for treatment-related fluctuation: clinical documentation must be submitted to indicate very severely affected patient with no improvement or further deterioration at 2 weeks since initial treatment.

Requirements for Immunoglobulin (Human) Products (IVIG, IMIG, SCIG)

Medical Billing:

A) Accepted HCPCS codes (with an approved TAR):

Product	HCPCS	HCPCS Description
Intravenous Infusion		
Alyglo	J1552	Injection, immune globulin (alyglo), 500 mg
Yimmugo	J1553	Injection, immune globulin (yimmugo), 100 mg
Asceniv	J1554	Injection, immune globulin (asceniv), 500 mg
Bivigam	J1556	Injection, immune globulin (bivigam), 500 mg
Flebogamma; Flebogamma DIF	J1572	Injection, immune globulin, (flebogamma/flebogamma dif), intravenous, non-lyophilized (e.g., liquid), 500 mg
Gammagard S/D; Carimune NF	J1566	Injection, immune globulin, intravenous, lyophilized (e.g., powder), not otherwise specified, 500 mg
Gammaplex	J1557	Injection, immune globulin, (gammaplex), intravenous, non-lyophilized (e.g., liquid), 500 mg
Octagam	J1568	Injection, immune globulin, (octagam), intravenous, non-lyophilized (e.g., liquid), 500 mg
Panzyga	J1576	Injection, immune globulin (panzyga), intravenous, non-lyophilized (e.g., liquid), 500 mg
Privigen	J1459	Injection, immune globulin (privigen), intravenous, non-lyophilized (e.g., liquid), 500 mg
Either Intravenous or Subcutaneous Infusion, depending on diagnosis for use		
Gammagard	J1569	Injection, immune globulin, (gammagard liquid), non-lyophilized, (e.g., liquid), 500 mg • IV or SC: Primary Immunodeficiency • IV only: All other indications
Gammaked; Gamunex-C	J1561	Injection, immune globulin, (gamunex-c/gammaked), non-lyophilized (e.g., liquid), 500 mg • IV or SC: Primary Immunodeficiency • IV only: All other indications
Intramuscular Injection		
GamaSTAN S/D	J1460	Injection, gamma globulin, intramuscular, per 1 cc
	J1560	Injection, gamma globulin, intramuscular, per 10 cc
Subcutaneous Infusion		
Cutaquig	J1551	Injection, immune globulin (cutaquig), 100 mg
Cuvitru	J1555	Injection, immune globulin (cuvitru), 100 mg
Hizentra	J1559	Injection, immune globulin (hizentra), 100 mg
Hyqvia	J1575	Injection, immune globulin/hyaluronidase, (hyqvia), 100 mg immune globulin
Xembify	J1558	Injection, immune globulin (xembify), 100 mg

B) General dosing information, by indication – a compilation from the drug monographs available through Wolters Kluwer Facts & Comparisons®

Indication	Dosing
FDA Approved Indications	
Antiviral prophylaxis	Dosing and frequency determined by wt (kg), type (Hepatitis A, measles, varicella) and time of potential exposure, current IVIG products used to treat the patient.
Chronic inflammatory demyelinating polyneuropathy	Initial: 2 g/kg IV divided in doses over 2-5 days or 400 mg/kg IV once a day for 5 days (max daily dose of 1 g/kg). Maintenance: 1 g/kg IV divided over 1-2 days every 3 weeks. Transitioning to SC: Start 1 week after last IVIG infusion, at 200 mg/kg – 400 mg/kg per week, over 1-2 sessions over 1 to 2 days.

Requirements for Immunoglobulin (Human) Products (IVIG, IMIG, SCIG)

Indication	Dosing
FDA Approved Indications, continued	
Dermatomyositis/polymyositis, severe, life threatening or refractory	1 g/kg per day IV x 2 days every 4 weeks or 1 g/kg per day once every 2 weeks
Hypogammaglobulinemia prophylaxis against bacterial infection	Acquired secondary to malignancy: 200 mg/kg – 400 mg/kg IV once every 3-4 weeks Primary humoral immunodeficiency disorder: 200 mg/kg – 800 mg/kg IV once every 3-4 weeks
Immune thrombocytopenia	≥ 18 yrs: 1 g/kg IV once a day for 1 -2 days, may hold second dose with adequate platelet response (eg, plt > 50,000 mm^3) after 24 hrs or 400 mg/kg IV daily x 5 days 2-17 yrs: Dose is dependent on product used for treatment, age, wt (kg) and dosing frequency chosen for acute or chronic treatment.
Kawasaki Syndrome	Infants and children (specific age range in not referenced): 2000 mg/kg IV over 8-12 hr, given within 10 days of disease onset. If signs and symptoms persist ≥ 36 hrs, 1000 mg/kg – 2000 mg/kg may be considered.
Multifocal motor neuropathy	Initial dosing: 2 g/kg IV divided over 2-5 consecutive days or 400 mg/kg IV once a day x 5 days (max daily dose: 1 g/kg) and maintenance dose of 1 g/kg – 2 g/kg every 2-6 weeks or if high dose was tolerated dosing 1 g/kg IV once daily x 2 days can be considered.
Off-Label Indications	
Pemphigus foliaceus and vulgaris, refractory	2 g/kg IV given in divided doses over 2-5 days or 400 mg/kg IV once a day x 5 days. May repeat every 4-6 weeks based on clinical response.
Guillain-Barré syndrome	Start treatment within 4 weeks of symptoms. 400 mg/kg IV x 5 days only. Retreatment is not recommended.
Myasthenia gravis, acute exacerbation	2 g/kg IV administered in divided doses given over 2-5 consecutive days or 400 mg/kg IV once a day x 5 days or 1 g/kg IV once a day for 2 days.
Toxic shock syndrome, streptococcal (adjunctive agent)	1 g/kg IV on day 1, followed by 500 mg/kg IV once daily on days 2 and 3
	Heart transplantation: 2 g/kg IV divided in 2-4 doses, given on consecutive days. If plasmapheresis is utilized, give 100 mg/kg IV after each session. This regimen may be repeated monthly if needed. Kidney transplantation: <1 year after transplant: 1 g/kg – 2.4 g/kg IV in divided doses over 1-3 consecutive days (max daily dose of 1 g/kg). If plasmapheresis is utilized, give 100 mg/kg IV after each session and remaining total dose after final session over 1-2 days. >1 year after transplant: 200 mg/kg IV every 2 weeks for 3 doses Lung transplant: 500 mg.kg – 2 g/kg IV (doses >1 g/kg are usually divided into 2 doses given over 2 days) and may be repeated monthly if needed.

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