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.

1. Requirements for Benralizumab (Fasenra™ AutoInjector Pen & Fasenra™ Prefilled Syringe)
2. Requirements for Requirements for Daptomycin (xellia), unrefrigerated, not therapeutically equivalent to J0878 or J0873, 1 mg
3. Requirements for Lumasiran (Oxlumo™)
4. Requirements for Pediatric GNRH agents: Fensolvi™, Triptodur™ and Supprelin LA™
5. Requirements for Requirements for Delandistrogene moxeparvovec-rokl (Elevidys™)

Requirements for Benralizumab (Fasenra™ AutoInjector Pen & Fasenra™ 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 with an eosinophilic phenotype. • Eosinophilic granulomatosis with polyangiitis (Churg-Strauss or EGPA)
Exclusion Criteria	• Monotherapy use (benralizumab is add on therapy to the current asthma treatment regimen) • Benralizumab will not be used concurrently with other monoclonal antibodies with similar indications such as dupilumab, mepolizumab, omalizumab, reslizumab or tezepelumab
Required Medical Information	Must submit clinical documentation to substantiate the following per diagnosis: For severe eosinophilic asthma: 1) Patient has a diagnosis of severe asthma with an eosinophilic phenotype and has a blood eosinophil counts equal to or greater than 150 cells/µL 2) Patient has persistent uncontrolled asthma despite at least 3 months of compliant use of high-dose inhaled corticosteroid (ICS) combined with long-acting β2 agonist (LABA) (ICS-LABA) as defined by at least one of the following: a. An Asthma Control Questionnaire (ACQ) score of 1.5 or more, or an Asthma Control Test (ACT) score less than 20 at baseline b. At least two exacerbations in the previous year. c. A history of Emergency Department (ED) visits requiring use of oral/systemic corticosteroids and/or hospitalization in the past year 3) Reduced lung function at baseline [pre-bronchodilator FEV1 below 80% in adults, and below 90% in adolescents] State the specific dosage form that will be administered during the medical office visit: a. Fasenra™ Autoinjector pen (may be administered by patient or caregiver with proper training) OR b. Fasenra™ Prefilled syringe (administered by health care provider) For eosinophilic granulomatosis with polyangiitis (Churg-Strauss or EGPA) 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 of total leukocyte count). 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. Anti-neutrophil cytoplasmic antibody (ANCA) positivity 3) Member has had at least one relapse (requiring an increase in oral corticosteroids dose, initiation/increased dose of immunosuppressive therapy or hospitalization) within 2 years prior to starting treatment with Fasenra or has refractory disease.

Requirements for Benralizumab (Fasenra™ AutoInjector Pen & Fasenra™ Prefilled Syringe)

Age Restriction	Asthma: 6 years and older EGPA: 18 years and older
Prescriber Restriction	None
Coverage Duration	Prefilled syringes: 3 doses (3 months) to allow administration of loading doses and for self-administration training with the goal of transitioning to the autoinjector pen for maintenance treatment at home (provided by the pharmacy). Autoinjector pens: 1 time dose for training & observation of self-administration technique.
Other Requirements & Information	Benralizumab (Fasenra™) is available for self-administration in the form of an auto-injector and is typically administered by the member or a caregiver at home. As soon as the maintenance dose is established and member or caregiver can be trained for self-administration, Fasenra™ autoinjector should be provided to the member by a pharmacy for administration at home whenever possible. Prefilled syringes: Requests will be approved for up to 3 months, if the healthcare provider prefers to administer the loading dose for new start requests, by obtaining it though the practice until maintenance dose and safety of self-administration is determined. Autoinjector pens: Requests will be approved for one-time to allow training of the member &/or caregiver on self-administration. Continuing to provide 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
J0517	Injection, benralizumab, per 1 mg (Fasenra™ auto-injector pen & Fasenra™ prefilled syringe)	Asthma: 30 mg subcutaneously every 4 weeks x 3 doses, and then once every 8 weeks thereafter. EGPA: 30 mg subcutaneously every 4 weeks Maximum Dose: 30 mg (30 HCPCS units)

Requirements for Daptomycin (xellia), unrefrigerated, not therapeutically equivalent to J0878 or J0873, 1 mg

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) Trial and failure or medical reasons why preferred daptomycin products billed with the following codes: J0878, J0877, J0874 and J0873 cannot be used. 2) Culture and Sensitivity lab report(s) when appropriate 3) Patient Med Allergy list if relevant 4) Treatment history for same infection 5) 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 • Linezolid <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
Age Restriction	≥ 1 year
Prescriber Restriction	None
Coverage Duration	Duration depends on diagnosis and treatment plan

Requirements for Daptomycin (xellia), unrefrigerated, not therapeutically equivalent to J0878 or J0873, 1 mg

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 Lumasiran (Oxlumo™)

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 primary hyperoxaluria type 1 (PH1) to lower urinary oxalate levels.
Exclusion Criteria	History of kidney or liver transplant. History of extrarenal systemic oxalosis.
Required Medical Information	Clinical documentation confirming: 1) Diagnosis of PH1 by: a. Genetic test to confirm mutation of alanine-glyoxylate aminotransferase (AGXT) gene, OR b. Liver biopsy demonstrating absent or decreased alanineglyoxylate aminotransferase (AGT) enzyme activity, if genetic test is unable to confirm mutation. 2) Baseline metabolic screening: a. 24-hour urinary oxalate excretion >0.7 mmol/1.7 3mm2/day, OR b. Urinary oxalate-to-creatinine ratio greater than upper limit of normal (ULN) for age, OR c. Elevated urinary excretion of glycolate. 3) Trial and failure to at least 3-month therapy of pyridoxine (vitamin B6) at maximum tolerated dose (up to 20 mg/kg/day). 4) Current weight. 5) For members over the age of 9 years and with eGFR >30ml/1.73mm^2/min: documentation of a trial and failure, or reasons why self-administered nedosiran (Rivfloza) cannot be used.
Age Restriction	None
Prescriber Restriction	Prescribed by (or in consultation with) an endocrinologist, nephrologist, or urologist
Coverage Duration	Initial: 6 months. Renewal: 12 months upon documentation of positive clinical treatment response when compared to pre-treatment baseline.
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		
J0224	Injection, lumasiran, 0.5mg	Maximum dose: 6 mg/kg in a single date of service. Example: 80 kg patient would be billed as no more than 960 HCPCS units (480 mg).		
		Weight	Loading Dose	Maintenance Dose
		< 10kg	6mg/kg SC once monthly for 3 doses	2mg/kg SC once monthly
		10 to <20kg	6mg/kg SC once monthly for 3 doses	6mg/kg SC once every 3 months
		≥20kg	3mg/kg SC once monthly for 3 doses	3mg/kg SC once every 3 months

Requirements for Pediatric GNRH agents: Fensolvi™, Triptodur™ and Supprelin LA™

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	• Central precocious puberty (CPP) • Gender incongruence; puberty suppression
Exclusion Criteria	Peripheral precocious puberty
Required Medical Information	Documentation of the following must be submitted per diagnosis: Central Precocious Puberty 1. Specialist consult notes documenting diagnosis of CPP and treatment plan. 2. Baseline height and weight, growth velocity, bone age test results (within the past year). 3. Documentation of trial and failure, or contraindication to, PHC's preferred GnRH agonist, Lupron Depot. Gender Incongruence; Puberty Suppression: 1. Evaluation by a mental health professional or other health care professional who has the appropriate experience and training in treating gender incongruence. 2. Confirmation of the following: a. Well-documented gender dysphoria/gender incongruence. b. Stability of relevant medical and mental health. 3. Documentation that member has experienced puberty development to at least Tanner stage 2. 4. Documentation that pubertal changes have negatively affected member's psychological or social functioning due to increased gender dysphoria. 5. Documentation of trial and failure, or contraindication to, PHC's preferred GnRH agonist, Lupron Depot.
Age Restriction	-Central Precocious Puberty: ≥1 yr and ≤11 yrs for females; ≤12 yrs for males -Gender incongruence: adolescents who have experienced puberty development to at least Tanner stage 2.
Prescriber Restriction	-Central Precocious Puberty: Endocrinologist -Gender incongruence: Endocrinologist or other specialist with appropriate training and experience treating gender incongruence in adolescents.
Coverage Duration	-Central Precocious Puberty: 12 months, until the resumption of puberty is desired. Renewal requests require current bone age, growth velocity, height, weight and clinic note with assessment of pubertal progression. Gender incongruence: 12 months. Renewal requests require documentation of positive response from treatment and continued medical necessity.
Other Requirements & Information	Requests for off-label use: See PHC criteria document *Case-by-Case TAR Requirements and Considerations.*

Requirements for Pediatric GNRH agents: Fensolvi™, Triptodur™ and Supprelin LA™

Medical Billing:

Dose limits & billing requirements, with an approved TAR:

HCPCS	Description	Dosing, Units
J3316	Injection, triptorelin, extended release, 3.75 mg	22.5 mg once every 24 weeks.
J9226	Histrelin implant (supprelin la), 50 mg	50 mg implant inserted every 12 to 24 months.
J1951	Injection, leuprolide acetate for depot suspension (fensolvi), 0.25 mg	45 mg once every 6 months.

Requirements for Delandistrogene moxeparvovec-rokl (Elevidys™)

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 Duchenne muscular dystrophy (DMD) with a confirmed mutation in the DMD gene.
Exclusion Criteria	1. Treatment or use for anything other than DMD 2. Prior administration of delandistrogene moxeparvovec-rokl (Elevidys™) 3. Deletions in exon 8 and/or exon 9 in the DMD gene 4. Concurrent use with exon skipping therapies
Required Medical Information	1. Documented diagnosis of Duchenne muscular dystrophy with medical records detailing the clinical course and confirming a mutation of the DMD gene. a. Genetic mutation test results must be submitted with request. b. Skeletal muscle biopsy results characterizing dystrophin by western blot and immunohistochemistry may be required, such as in the case of genetic testing showing a variant of uncertain significance, or a clinical course and laboratory findings deviating from the traditional trajectory of DMD. c. For mutations in exons 1-17, provider must attest that they are aware of the increased risk for severe myositis associated with these mutations. 2. Baseline Serum Creatine Kinase level with laboratory reference range. 3. Documentation of ambulatory status in the medical records AND as evidenced by North Star Ambulatory Assessment (NSAA) score of ≥1 (or equivalent on another recognized scale) completed within the 3 months prior to TAR submission. 4. Documentation of anti-AAVrh74 total antibody titers <1:400 using a Total Binding Antibody enzyme linked immunosorbent assay (ELISA) completed within the 30 days prior to TAR submission. 5. Documentation of baseline liver function tests, platelet counts, left ventricular ejection fraction (LVEF) and troponin I levels completed within the 30 days prior to TAR submission. Elevidys administration should be postponed until acute liver disease has resolved or been controlled. 6. Documentation that the member does not have any signs or symptoms of infection. 7. Concurrent use corticosteroids (prednisone, prednisolone, deflazacort (Emflaza™), vamorolone (Agamree™) etc.) at a stable dose for at least 12 weeks, unless contraindicated or intolerant. 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	Ages 4 years and older

Requirements for Delandistrogene moxeparvovec-rokl (Elevidys™)

Prescriber Restriction	Prescribed by, or under supervision and monitoring of a neurologist or a provider who specializes in the treatment of Duchenne muscular dystrophy
Coverage Duration	Once per lifetime
Other Requirements & Information	Requests for use in members who are considered non-ambulatory: See PHC criteria document ***Case-by-Case TAR Requirements and Considerations.*** Prescriber must attest or otherwise document member will receive prophylactic prednisolone (or glucocorticoid equivalent) (in addition to baseline corticosteroid dose) one day prior to Elevidys™ infusion and for 60 days following therapy to monitor liver function.

Medical Billing:

Dose limits & billing requirements, with an approved TAR:

HCPCS	Description	Dosing, Units
J1413	Injection, delandistrogene moxeparvovec-rokl, per therapeutic dose (Elevidys™)	$1.33x10^{14}$ vector genomes per kg (vg/kg) of body weight (or 10mL/kg) Supplied in 10ml vials packaged into single dose kits ranging from 10 to 70 vials per kit.