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.

Canakinumab (Ilaris™)	Axibotuinumtoxina-lanm (Daxxify™)	Sodium hyaluronate (Euflexxa™)	Sodium hyaluronate (Gel-One™)
Tofersen (Qalsody™)	Viltolarsen (Viltepso™)	Sodium hyaluronate (Hyalgan™)	Sodium hyaluronate (Genvisc 850™)
Eteplirsen (Exondys-51™)	Tedizolid (Sivextro™)	Sodium hyaluronate (Supartz FX™)	Hyaluronan (Hymovis™)
Casimersen (Amondys-45™)	Oritavancin (Orbactiv™)	Sodium hyaluronate (Visco 3™)	Hyaluronan (Monovisc™)
Golodirsen (Vyondys 53™)	Dalbavancin (Dalvance™)	Hylan g-f 20 (Synvisc™)	Hyaluronan (Orthovisc™)
Nusinersen (Spinraza™)	Daptomycin (Cubicin™)	Hylan g-f 20 (Synvisc-One™)	Sodium hyaluronate (synojoynt™)
Delandistrogene moxeparvovec-rokl (Elevidys™)	Onasemnogene Abeparvovec-xioi (Zolgensma™)	Sodium hyaluronate (Gelsyn-3™)	Sodium hyaluronate (Triluron™)
		Sodium hyaluronate (Durolane™)	Sodium hyaluronate (Trivisc™)

Requirements for Canakinumab (Ilaris™)

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	• Periodic Fever Syndromes: Cryopyrin-associated periodic syndromes (CAPS); Familial Mediterranean fever (FMF); Hyperimmunoglobulin D Syndrome (HIDS)/Mevalonate Kinase Deficiency (MKD); Tumor necrosis factor (TNF) receptor associated periodic syndrome TRAPS). • Adult Onset Still's Disease (AOSD). • Systemic Juvenile Idiopathic Arthritis (SJIA). • Gout, treatment, acute flares.
Exclusion Criteria	
Required Medical Information	For all indications: 1) Specialist's clinic notes documenting disease course with evidence of active disease &/or inflammation as appropriate by diagnosis (imaging, labs, or other findings as indicated). Please include all prior therapies tried and failed prior to request for canakinumab. 2) Treatment plan which includes patient's weight and medication dosing interval requested. 3) Member is not receiving concurrent treatment with TNF inhibitors or other Interleukin-1 inhibitors. Periodic Fever Syndromes: 1) For the treatment of CAPS- Member has diagnosis of one of the following: a. Familial cold autoinflammatory syndrome (FCAS), b. Muckle-Wells syndrome (MWS), c. Chronic infantile neurological cutaneous and articular (CINCA) syndrome or neonatal-onset multisystem inflammatory disease (NOMID). 2) For the treatment FMF- ALL of the following criteria apply: a. Member has diagnosis of FMF with documentation of at least one flare per month, or hospitalization for a severe flare, despite use, or contraindication to, maximally tolerated dose of colchicine for a minimum of 6 months. Adherence to colchicine therapy to be confirmed through pharmacy fill records. b. CRP level ≥10 or at least two times the upper limit of normal per lab analysis and c. Member will continue to take colchicine in combination with canakinumab (unless contraindication to). 3) For the treatment of HIDS/MKD- ALL of the following criteria apply: a. IgD level to confirm diagnosis (or genetic testing for MVK gene if indicated). b. Member with frequent disease flares (≥3 within the previous 6 months) or hospitalization for a severe flare. c. CRP level ≥10 or at least two times the upper limit of normal per lab analysis. 4) For the treatment of TRAPS- Documentation that member has been diagnosed with TRAPS and meets one or more of the following criteria (high risk factors for amyloidosis): a. Member has frequent attacks (more than 6 per year) or hospitalization for a severe flare. b. Persistent elevation of inflammatory markers (CRP, ESR) between attacks. c. Inadequate response to oral glucocorticoids. d. Pathogenic *TNFRSF1A* variant.

Requirements for Canakinumab (Ilaris™)

	e. Evidence of secondary (AA) amyloidosis. Still's Disease, including adult-onset Still's disease (AOSD) and systemic juvenile idiopathic arthritis (SJIA)- Documentation of ANY of the following: 1) Clinically significant serositis (e.g., pleurisy or peritonitis). 2) Moderate to severe debilitating polyarthritis. 3) Persistent high fevers despite use, or contraindication to, an adequate trial of NSAIDs, glucocorticoids, or methotrexate. a. Adequate trial consists of 1 month of NSAIDs (e.g., naproxen, ibuprofen), 2 weeks of systemic glucocorticoids (e.g., prednisone), or 3 months of methotrexate. 4) Internal organ involvement or other severe systemic symptoms. Gout, treatment of acute flares- ALL of the following criteria must be met: 1) Member has documented frequent flares (at least 3 flares in previous 12 months) in whom first-line therapies are ineffective, contraindicated, or not tolerated. 2) Member has been educated on and attempted lifestyle modifications that may contribute to gout flares (e.g., limiting alcohol use, dietary modification, discontinuance or changing other medications known to precipitate gout flares when possible). 3) Documentation of trial and failure, or contraindication to, treatment with ALL of the following per standard dosing for treating gout flares: a. NSAIDs b. colchicine c. glucocorticoids (oral, intraarticular, or intramuscular) 4) Member has tried and failed, or contraindication to, preferred IL-1 inhibitor, anakinra (Kineret™). 5) Member is being considered for urate lowering therapy if not already taking (e.g., allopurinol, febuxostat, probenecid). 6) Therapy is requested as a single 150 mg dose.
Age Restriction	Per FDA approved indication: 18 years and older for treating Gout. 2 years and older for treating CAPS, FMF, HIDS, MKD, TRAPS, SJIA/AOSD
Prescriber Restriction	Per specialist appropriate per indication: Periodic Fever Syndromes: • CAPS: Rheumatologist, Allergist, Immunologist, Geneticist, Dermatologist. • FMF: Rheumatologist, Nephrologist, Geneticist, Oncologist, Hematologist, Gastroenterologist. • HIDS/MKD: Rheumatologist, Nephrologist, Geneticist, Oncologist, Hematologist. • TRAPS: Rheumatologist, Nephrologist, Geneticist, Oncologist, Hematologist. Systemic Juvenile Idiopathic Arthritis/ Still Disease: Rheumatologist. Gout: Rheumatologist, Nephrologist.
Coverage Duration	For indications other than gout: initial approval up to 12 months with renewal duration up to 12 months per renewal. For the treatment of gout flares: 150 mg as single dose per request at a frequency interval of ≥ 12 weeks. Renewal with documentation that initial criteria for treating gout flares continues to be met and that member is taking, or has contraindication to, standard urate lowering therapies (e.g., allopurinol, febuxostat, probenecid).

Requirements for Canakinumab (Ilaris™)

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
J0638	Injection, canakinumab, 1 mg	FDA approved dose varies per indication and patient weight per package labeling. Average range of 150 mg to 300 mg every 4 to 8 weeks with potential max dose of 600 mg per infusion based off of patient response.

Requirements for Tofersen, intrathecal injection (Qalsody™)

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 the treatment of amyotrophic lateral sclerosis (ALS) in adults who have a mutation in the superoxide dismutase 1 (SOD1) gene
Exclusion Criteria	None
Required Medical Information	1) Clinic notes documenting diagnosis of ALS 2) Genetic testing confirming mutation in the superoxide dismutase 1 (SOD1) gene
Age Restriction	18 years and older
Prescriber Restriction	Neurologist
Coverage Duration	Initial: 6 months Renewal: 12 months
Other Requirements & Information	Renewal requests: Clinical documentation that tofersen use has slowed, stabilized or improved the member's overall function, relative to that projected for the natural course of ALS. 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
C9157	Injection, tofersen, 1 mg (Qalsody™)	100mg (100 units) intrathecally every 14 days for 3 doses, then every 28 days thereafter

Requirements for Eteplirsen (Exondys-51™)

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 the treatment of Duchenne muscular dystrophy (DMD) in patients who have a confirmed mutation of the DMD gene that is amenable to exon 51 skipping.
Exclusion Criteria	Use concomitantly with other exon skipping therapies for DMD
Required Medical Information	1. Documented diagnosis of Duchenne muscular dystrophy with medical records confirming a mutation of the DMD gene that is amenable to exon 51 skipping. 2. Genetic mutation test results must be submitted with request. 3. Concurrent use corticosteroids (prednisone, prednisolone, etc.) unless contraindicated or intolerant 4. Renal toxicity screening with urinalysis, creatinine/protein ration or serum cystatin C 5. Baseline documentation of the following: a. 6-minute walk test (6MWT) b. Upper limb function (ULM) test or Brooke Upper Extremity Rating Scale <5 c. Forced Vital Capacity (FVC) >30% 6. 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	None
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	Up to 12 months
Other Requirements & Information	RENEWAL: • Documentation based on the prescriber's assessment, the member continues to benefit from therapy and has positively responded to therapy compared to pretreatment baseline in one or more of the following (not all-inclusive): ○ Stability, improvement, or slowed rate of decline in 6MWT or other timed function tests ○ Stability, improvement, or slowed rate of decline in ULM test ○ Stability, improvement, or slowed rate of decline in FVC% predicted Initial and renewal requests must be for the FDA-approved dosage only. Requests for off-label use: See PHC criteria document ***Case-by-Case TAR Requirements and Considerations.***

Requirements for Eteplirsen (Exondys-51™)

Medical Billing:

Dose limits & billing requirements, with an approved TAR:

HCPCS	Description	Dosing, Units
J1428	Injection, eteplirsen, 10mg	30mg/kg body weight IV once weekly as a 35 to 60 minute intravenous infusion.

Related DHCS document: CCS Numbered Letter 11-1120, December 8, 2020

Requirements for Casimersen (Amondys-45®)

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) in patients who have a confirmed mutation of the DMD gene that is amenable to exon 45 skipping.
Exclusion Criteria	Use concomitantly with other exon skipping therapies for DMD
Required Medical Information	1. Documented diagnosis of Duchenne muscular dystrophy with medical records confirming a mutation of the DMD gene that is amenable to exon 45 skipping. a. Genetic mutation test results must be submitted with request. 2. Concurrent use corticosteroids [prednisone, prednisolone, deflazacort (Emflaza™), TAR is required for Medi-Cal Rx] 3. Baseline documentation of the following: a. 6-minute walk test (6MWT) b. Upper limb function (ULM) test or Brooke Upper Extremity Rating Scale <5 c. Forced Vital Capacity (FVC) >30% 4. Renal toxicity screening with urinalysis, creatinine/protein ration or serum cystatin C 5. Current weight 6. 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	None
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	Up to 12 months
Other Requirements & Information	<u>Renewal Requirements:</u> Documentation based on the prescriber's assessment that the member continues to benefit from Amondys 45® and has responded positively (eg, stability, improvement, or slowed rate of decline) to therapy compared to pretreatment baseline in one or more of the following: • 6MWT or other timed function tests • ULM test • FVC% predicted Initial and renewal requests must be for the FDA-approved dosage only.

Requirements for Casimersen (Amondys-45®)

Medical Billing:

Dose limits & billing requirements, with an approved TAR:

HCPCS	Description	Dosing, Units
J1426	Injection, caismersen, 10mg (Amondys 45™)	30mg/kg/dose qweek

Related DHCS document: CCS Numbered Letter 11-1120, December 8, 2020

Requirements for Nusinersen (Spinraza™)

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 spinal muscular atrophy (SMA)
Exclusion Criteria	Concurrent use with risdiplam (Evrysdi™)
Required Medical Information	1. Documentation required for: a. Symptomatic patients: i. Diagnosis of 5q SMA with documentation of genetic lab testing confirming homozygous deletion or any combination of survival motor neuron 1 (SMN1) deletions or point mutations AND ii. Number of copies of SMN2 b. Presymptomatic patients: i. Genetic lab testing to confirm homozygous SMN1 deletion or mutation. ii. ≤ 3 copies of SMN2 2. Age of onset 3. Documentation of at least one validated neuromotor assessment, performed within past 12 months with a score used to establish a clinical baseline. 4. Baseline pulmonary function tests (e.g. FVC, etc) for ages 4 years and older. 5. Documentation of consideration of less invasive oral treatment (risdiplam, Evrysdi™) and why it cannot be used, or documentation of trial and failure of risdiplam. 6. 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	None
Prescriber Restriction	Neurologist, or pediatric neurologist
Coverage Duration	Initial: 6 months. Renewal: 12 months with documentation of benefit with treatment
Other Requirements & Information	Renewal request requires, with assessment after initiation of treatment: 1. Current clinic notes (within the past 6 months) with assessment of patient, specifying neuromotor status and/or drug related toxicity. 2. Neuromotor assessment within 12 months of the reauthorization request, which demonstrates improvement or lack of deterioration. Requests for off-label use: See PHC criteria document ***Case-by-Case TAR Requirements and Considerations.***

Requirements for Nusinersen (Spinraza™)

Medical Billing:

Dose limits & billing requirements, with an approved TAR:

HCPCS	Description	Dosing, Units
J2326	Intrathecal solution, nusinersen, 0.1mg (SpinrazaTM)	Loading Dose: 12 mg q14 days for 3 doses, then 12 mg once 30 days after 3rd dose. Maintenance Dose:12 mg q4 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 ambulatory pediatric patients aged 4 through 5 years with 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. Mutations limited to exon 45 in the DMD gene 5. Concurrent use with exon skipping therapies
Required Medical Information	1. Documented diagnosis of Duchenne muscular dystrophy with medical records confirming a mutation of the DMD gene. a. Genetic mutation test results must be submitted with request b. 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. Documentation of ambulatory status as evidenced by North Star Ambulatory Assessment (NSAA) score of >17 (or equivalent on another recognized scale). 3. Documentation of anti-AAVrh74 total antibody titers <1:400 using a Total Binding Antibody enzyme linked immunosorbent assay (ELISA) 4. Documentation of baseline liver function tests, platelet counts and troponin I levels. Elevydys administration should be postponed until acute liver disease has resolved or been controlled. 5. Documentation that the member does not have any signs or symptoms of infection 6. Concurrent use corticosteroids (prednisone, prednisolone, deflazacort (Emflaza™) etc.) at a stable dose for at least 12 weeks, unless contraindicated or intolerant 7. 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 4-5 years old only
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	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.

Requirements for Delandistrogene moxeparvovec-rokl (Elevidys™)

Medical Billing:

Dose limits & billing requirements, with an approved TAR:

HCPCS	Description	Dosing, Units
J3590	Unclassified biologics: Delandistrogene moxeparvovec-rokl (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.

Requirements for Golodirsen (Vyondys 53™) and Viltolarsen (Viltepso™)

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 the treatment of Duchenne muscular dystrophy (DMD) in patients who have a confirmed mutation of the DMD gene that is amenable to exon 53 skipping.
Exclusion Criteria	Use concomitantly with other exon skipping therapies for DMD
Required Medical Information	1. Documented diagnosis of Duchenne muscular dystrophy with medical records confirming a mutation of the DMD gene that is amenable to exon 53 skipping. 2. Genetic mutation test results must be submitted with request. 3. Concurrent use corticosteroids (prednisone, prednisolone, etc.) unless contraindicated or intolerant 4. Renal toxicity screening with urinalysis, creatinine/protein ration or serum cystatin C 5. Baseline documentation of the following: a. 6-minute walk test (6MWT) b. Upper limb function (ULM) test or Brooke Upper Extremity Rating Scale <5 c. Forced Vital Capacity (FVC) >30% 6. 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	None
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	Up to 12 months
Other Requirements & Information	RENEWAL: • Documentation based on the prescriber's assessment, the member continues to benefit from therapy and has positively responded to therapy compared to pretreatment baseline in one or more of the following (not all-inclusive): ○ Stability, improvement, or slowed rate of decline in 6MWT or other timed function tests ○ Stability, improvement, or slowed rate of decline in ULM test ○ Stability, improvement, or slowed rate of decline in FVC% predicted Initial and renewal requests must be for the FDA-approved dosage only. Requests for off-label use: See PHC criteria document ***Case-by-Case TAR Requirements and Considerations.***

Requirements for Golodirsen (Vyondys 53™) and Viltolarsen (Viltepso™)

Medical Billing:

Dose limits & billing requirements, with an approved TAR:

Product	HCPCS	Description	Dosing, Units
Viltepso	J1427	Injection, viltolarsen, 10mg	80 mg/kg once weekly as a 60-minute intravenous infusion.
Vyondys 53	J1429	Injection, golodirsen, 10mg	30 mg/kg once weekly as 35 to 60-minute intravenous infusion via an in-line 0.2 micron filter.

Related DHCS document: CCS Numbered Letter 11-1120, December 8, 2020

Requirements for daxibotuinumtoxinA-lanm (Daxxify®)

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	Cervical dystonia
Exclusion Criteria	None
Required Medical Information	Documentation of cervical dystonia diagnosis
Age Restriction	18 years and older
Prescriber Restriction	Administered by a neurologist, orthopedist, or specialist in pain management, physical medicine, or rehabilitation (physiatrist, PMR).
Coverage Duration	Initial: 12 months Renewal: 12 months with documentation of benefit with treatment
Other Requirements & Information	Request for cosmetic purposes (e.g., treatment of brow furrows, wrinkles, forehead creases or other skin lines) are not a covered benefit. 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	125 units to 250 units, Daxxify® comes in 50 unit and 100 unit vials

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	1500 mg as a single dose regimen Or 1000 mg followed one week later by 500 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 • 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
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 Hyaluronic Acid, Group 1: Euflexxa™, Hyalgan™, Supartz FX™, Synvisc™, Synvisc–One™, Visco 3™, Gelsyn-3™, Durolane™

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 pain in osteoarthritis of the knee in patients who have failed non-pharmacologic treatment and simple analgesics.
Exclusion Criteria	• Treatment for pain in the knee due to causes other than osteoarthritis, such as gout, rheumatoid arthritis. • Treatment for pain management for area(s) other than knee.
Required Medical Information	Clinic Notes from specialist (see prescriber restriction) to confirm diagnosis of osteoarthritis of the knee with moderate to severe pain AND must meet each of: 1) Documentation of trial and failure of, at least 2 prescription strength oral NSAIDs, at adequate doses for at least a 1-month trial of each a. If intolerant to oral NSAIDs, must have at least a 1-month trial of topical diclofenac 1% gel or topical capsaicin. b. Note: a trial of duloxetine is also suggested prior to hyaluronic acid injections based on the 2019 American College of Rheumatology Osteoarthritis Guidelines. 2) Trial and failure of physical therapy and at least one non-pharmacological measure supported by osteoarthritis guidelines (e.g. knee braces, walking aids, weight loss intervention, mind-body exercise programs). 3) Documentation of trial with at least one intra-articular glucocorticoid injection.
Age Restriction	18 years and older
Prescriber Restriction	Pain management, Rheumatology and Orthopedics
Coverage Duration	New & Renewal: Approval limited to one treatment series per knee at intervals no more frequent than 6 months (even if brand/product is changed).
Other Requirements & Information	Renewal Request: Clinic notes must indicate efficacy with previous treatment series, with diminished response at time of renewal request. Requests for off-label use: See PHC criteria document *Case-by-Case TAR Requirements and Considerations.*

Requirements for Hyaluronic Acid, Group 1: Euflexxa™, Hyalgan™, Supartz FX™, Synvisc™, Synvisc–One™, Visco 3™, Gelsyn-3™, Durolane™

Medical Billing:
Dose limits & billing requirements, with an approved TAR:

Product	HCPCS	Description	Dosing, Units
Euflexxa™	J7323	Hyaluronan or derivative, euflexxa, for intra-articular injection, per dose	20mg q week x 3 (1 unit per DOS)
Hyalgan™	J7321	Hyaluronan or derivative, hyalgan, for intra-articular injection, per dose	20mg q week x 5 (1 unit per DOS)
Supartz FX™		Hyaluronan or derivative, Supartz FX, for intra-articular injection, per dose	25mg q week x 5 (1 unit per DOS)
Visco 3™		Hyaluronan or derivative, visco-3, for intra-articular injection, per dose	25mg q week x 3 (1 unit per DOS)
Synvisc™ & Synvisc-One™	J7325	Hyaluronan or derivative, synvisc or synvisc-one, for intra-articular injection, 1 mg	48mg x 1 (48 unit per DOS)
Gelsyn-3™	J7328	Hyaluronan or derivative, gelsyn-3, for intra-articular injection, 0.1 mg	16.8mg q week x 3 (168 units per DOS)
Durolane™	J7318	Hyaluronan or derivative, durolane, for intra-articular injection, 1 mg	60mg once (60 units per DOS)

Requirements for Hyaluronic Acid, Group 2: Gel-One™, Genvisc 850™, Hymovis™, Monovisc™, Orthovisc™, SynoJoynt™, Triluron™, Trivsic™

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 pain in osteoarthritis of the knee in patients who have failed non-pharmacologic treatment and simple analgesics.
Exclusion Criteria	• Treatment for pain in the knee due to causes other than osteoarthritis, such as gout, rheumatoid arthritis. • Treatment for pain management for area(s) other than knee.
Required Medical Information	Clinic Notes from specialist (see prescriber restriction) to confirm diagnosis of osteoarthritis of the knee with moderate to severe pain AND must meet each of: 1) Documentation of trial and failure of, at least 2 prescription strength oral NSAIDs, at adequate doses for at least a 1-month trial of each a. If intolerant to oral NSAIDs, must have at least a 1-month trial of topical diclofenac 1% gel or topical capsaicin. b. Note: a trial of duloxetine is also suggested prior to hyaluronic acid injections based on the 2019 American College of Rheumatology Osteoarthritis Guidelines. 2) Trial and failure of physical therapy and at least one non-pharmacological measure supported by osteoarthritis guidelines (e.g., knee braces, walking aids, weight loss intervention, mind-body exercise programs). 3) Documentation of trial with at least one intra-articular glucocorticoid injection. 4) Documentation of trial and failure to 2 preferred products (PA Group 1, a-f): a. Durolane™ b. Euflexxa™ c. Gelsyn-3™ d. Hyalgan™ e. Supartz FX™ f. Synvisc™, Synvisc-One™ g. Visco 3™
Age Restriction	18 years and older
Prescriber Restriction	Pain management, Rheumatology and Orthopedics
Coverage Duration	New & Renewal: Approval limited to one treatment series per knee at intervals no more frequent than 6 months (even if brand/product is changed).
Other Requirements & Information	Renewal Request: Clinic notes must indicate efficacy with previous treatment series, with diminished response at time of renewal request. Requests for off-label use: See PHC criteria document *Case-by-Case TAR Requirements and Considerations.*

Requirements for Hyaluronic Acid, Group 2: Gel-One™, Genvisc 850™, Hymovis™, Monovisc™, Orthovisc™, SynoJoynt™, Triluron™, Trivsic™

Medical Billing:

Dose limits & billing requirements, with an approved TAR:

Product	HCPCS	Description	Dosing, Units
Gel-One™	J7326	Hyaluronan or derivative, gel-one, for intra-articular injection, per dose	30mg once (1 units per DOS)
Genvisc 850™	J7320	Hyaluronan or derivitive, genvisc 850, for intra-articular injection, 1 mg	25mg q week x 5 (25 units per DOS)
Hymovis™	J7322	Hyaluronan or derivative, hymovis, for intra-articular injection, 1 mg	24mg q week x 2 (24 units per DOS)
Monovisc™	J7327	Hyaluronan or derivative, monovisc, for intra-articular injection, per dose	88mg x 1 (1 unit per DOS)
Orthovisc™	J7324	Hyaluronan or derivative, orthovisc, for intra-articular injection, per dose	30mg q week x 3 (1 unit per DOS)
SynoJoynt™	J7331	Hyaluronan or derivative, synojoynt, for intra-articular injection, 1 mg	20mg q week x 3 (20 units per DOS)
Triluron™	J7332	Hyaluronan or derivative, triluron, for intra-articular injection, 1 mg	20mg q week x3 (20 units per DOS)
Trivisc™	J7329	Hyaluronan or derivative, trivisc, for intra-articular injection, 1 mg	25mg q week x3 (25 units per DOS)

Requirements for Onasemnogene Abeparvovec-xioi (Zolgensma™)

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 the treatment of pediatric patients less than 2 years of age with spinal muscular atrophy (SMA) with bi-allelic mutations in the survival motor neuron 1 (SMN1) gene.
Exclusion Criteria	1. Concurrent treatment with nusinersen (Spinraza™) or risdiplam (Evrysdi™). 2. Treatment or use for anything other than SMA
Required Medical Information	1. Diagnosis of 5q spinal muscular atrophy with documentation of genetic testing confirming bi-allelic mutations in SMN1 gene (deletions or point mutations) AND documentation of up to and including four copies of SMN2. 2. Member does not have advanced SMA disease as evidence by: a. complete paralysis of limbs b. Invasive ventilation or tracheostomy 3. Member must have an anti-AAV9 antibody titer below or equal to (<) 1:50 as determined by Enzyme-Linked Immunosorbent Assay (ELISA) binding immunoassay within 90 days of planned administration. 4. Documentation supporting no indication of significant liver injury 5. Documentation of baseline liver function test, platelet counts, and troponin-I. 6. Documentation of at least one neuromotor assessment, performed within past 12 months with a score used to establish a clinical baseline. 7. Member must not have received this therapy previously. 8. 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	Under the age of two years
Prescriber Restriction	Neurologist or pediatric neurologist
Coverage Duration	Once per lifetime
Other Requirements & Information	Prescriber must attest or otherwise document member will receive prophylactic prednisolone (or glucocorticoid equivalent) one day prior to Zolgensma infusion and for 30 days following therapy to monitor liver function. Treatment with nusinersen or risdiplam must be discontinued prior to the administration of onasemnogene abeparvovec

Requirements for Onasemnogene Abeparvovec-xioi (Zolgensma™)

Medical Billing:

Dose limits & billing requirements, with an approved TAR:

HCPCS	Description	Dosing, Units
J3399	Injection, onasemnogene abeparvovec-xioi, per treatment, up to 5x10^15 vector genomes	1.1 × 1014 vector genomes per kilogram (vg/kg) of body weight.

Administer ZOLGENSMA as a single-dose intravenous infusion through a venous catheter over 60 minutes.

Related DHCS document: CCS Numbered Letter 15-1120, November 19, 2020