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Medical Policy Update Bulletin: December 2022

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Annual CPT® and HCPCS Code Updates

Beginning Jan. 1, 2023, all applicable Medical Policies, Medical Benefit Drug Policies, Coverage Determination Guidelines, and Utilization Review Guidelines will be updated to reflect the 2023 Current Procedural Terminology (CPT®) and Healthcare Common Procedure Coding System (HCPCS) code additions, revisions, and deletions. Refer to the following sources for information on the code updates:

- American Medical Association. Current Procedural Terminology: CPT®
- Centers for Medicare & Medicaid Services. Healthcare Common Procedure Coding System: HCPCS Level II

Complete details on impacted policies and corresponding code edits will be provided in the January 2023 edition of the Medical Policy Update Bulletin.

Updated			
Policy Title	**Effective Date**	**Summary of Changes**	
Obstetrical Ultrasound	Jan. 1, 2023	Applicable Codes • Added ICD-10 diagnosis codes O20.0, O09.01, and O09.811 Supporting Information • Updated *Clinical Evidence* and *References* sections to reflect the most current information	
Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Catheter Ablation for Atrial Fibrillation	Jan. 1, 2023	Coverage Rationale • Added language to indicate this policy does not apply to members ages < 18 years or to arrhythmias other than atrial fibrillation • Revised language pertaining to medical necessity clinical coverage criteria; replaced reference to the "InterQual® CP: Procedures, Electrophysiology (EP) Testing +/- Radiofrequency Ablation (RFA), Cardiac" with "InterQual® CP: Procedures, Electrophysiology (EP) Testing +/- Radiofrequency Ablation (RFA) *or Cryothermal Ablation*, Cardiac"	Note: This policy does not apply to members ages < 18 years or to arrhythmias other than atrial fibrillation. Catheter ablation for atrial fibrillation is proven and medically necessary in certain circumstances. For medical necessity clinical coverage criteria, refer to the InterQual® CP: Procedures, Electrophysiology (EP) Testing +/- Radiofrequency Ablation (RFA) or Cryothermal Ablation, Cardiac. Click here to view the InterQual® criteria.
Gender Dysphoria Treatment	Jan. 1, 2023	Coverage Rationale • Revised list of indications for surgical treatment for Gender Dysphoria; replaced "breast surgery" with "*mastectomy*/breast *reduction* surgery" • Revised criteria that must be documented in the written psychological assessment for genital surgery; replaced criterion	Notes: • This Medical Policy does not apply to individuals with ambiguous genitalia or disorders of sexual development. • This Medical Policy does not apply to fully-insured group plans in California. Refer to the Benefit Interpretation Policy titled Gender Dysphoria (Gender Identity Disorder) Treatment: CA. • This Medical Policy does not apply to fully-insured group plans in the state of Washington. Refer to the Benefit Interpretation Policy titled Gender Dysphoria (Gender Identity Disorder) Treatment: WA.

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Gender Dysphoria Treatment (continued)	Jan. 1, 2023	requiring an individual must: ○ "Complete at least 12 months of successful continuous full-time real-life *experience* in the *desired* gender" with "complete at least 12 months of successful continuous full-time real-life *involvement* in the *experienced* gender" ○ "Complete 12 months of continuous *cross-sex* hormone therapy appropriate for the *desired* gender (unless medically contraindicated)" with "complete 12 months of continuous hormone therapy appropriate for the *experienced* gender (unless medically contraindicated *or not indicated for gender*)" • Added language for plans that specifically provide coverage for breast augmentation, thyroid cartilage reduction, and/or voice modification surgery (e.g., laryngoplasty, glottoplasty, or shortening of the vocal cords) to indicate a written psychological assessment from at least one Qualified Behavioral Health Provider experienced in treating Gender Dysphoria is required; the assessment must document that	Surgical treatment for Gender Dysphoria may be indicated for individuals who provide the following documentation: • For mastectomy/breast reduction surgery, a written psychological assessment from at least one Qualified Behavioral Health Provider experienced in treating Gender Dysphoria is required. The assessment must document that an individual meets all of the following criteria: ○ Persistent, well-documented Gender Dysphoria ○ Capacity to make a fully informed decision and to consent for treatment ○ Must be at least 18 years of age (age of majority) ○ Favorable psychosocial-behavioral evaluation to provide screening and identification of risk factors or potential postoperative challenges • For genital surgery, a written psychological assessment from at least two Qualified Behavioral Health Providers experienced in treating Gender Dysphoria, who have independently assessed the individual, is required. The assessment must document that an individual meets all of the following criteria: ○ Persistent, well-documented Gender Dysphoria ○ Capacity to make a fully informed decision and to consent for treatment ○ Must be at least 18 years of age (age of majority) ○ Favorable psychosocial-behavioral evaluation to provide screening and identification of risk factors or potential postoperative challenges ○ Complete at least 12 months of successful continuous full-time real-life involvement in the experienced gender ○ Complete 12 months of continuous hormone therapy appropriate for the experienced gender (unless medically contraindicated or not indicated for gender) ○ Treatment plan that includes ongoing follow-up and care by a Qualified Behavioral Health Provider experienced in treating Gender Dysphoria • For plans that specifically provide coverage for breast augmentation, thyroid cartilage reduction, and/or voice modification surgery (e.g., laryngoplasty, glottoplasty or shortening of the vocal cords), a written psychological assessment from at least one Qualified Behavioral Health Provider experienced in treating Gender Dysphoria is required. The assessment must

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Gender Dysphoria Treatment (continued)	Jan. 1, 2023	an individual meets all of the following criteria: ○ Persistent, well-documented Gender Dysphoria ○ Capacity to make a fully informed decision and to consent for treatment ○ Must be at least 18 years of age (age of majority) ○ Favorable psychosocial-behavioral evaluation to provide screening and identification of risk factors or potential postoperative challenges ○ For breast augmentation, completion of 12 months of continuous hormone therapy prior to the breast procedure is required • Removed notation pertaining to completion of hormone therapy prior to the breast procedure when bilateral mastectomy or breast reduction is performed as a stand-alone procedure, without genital reconstruction procedures • Added notation to clarify that some plans may provide coverage for specific ancillary procedures otherwise considered cosmetic; refer to the *Benefit Considerations* section of the policy, as member	document that an individual meets all of the following criteria: ○ Persistent, well-documented Gender Dysphoria ○ Capacity to make a fully informed decision and to consent for treatment ○ Must be at least 18 years of age (age of majority) ○ Favorable psychosocial-behavioral evaluation to provide screening and identification of risk factors or potential postoperative challenges ○ For breast augmentation, completion of 12 months of continuous hormone therapy prior to the breast procedure is required When the above criteria are met, the following surgical procedures to treat Gender Dysphoria are medically necessary and covered as a proven benefit: • Bilateral mastectomy or breast reduction • Clitoroplasty (creation of clitoris) • Hysterectomy (removal of uterus) • Labiaplasty (creation of labia) • Laser or electrolysis hair removal in advance of genital reconstruction prescribed by a physician for the treatment of Gender Dysphoria • Metoidioplasty (creation of penis, using clitoris) • Orchiectomy (removal of testicles) • Penectomy (removal of penis) • Penile prosthesis • Phalloplasty (creation of penis) • Salpingo-oophorectomy (removal of fallopian tubes and ovaries) • Scrotoplasty (creation of scrotum) • Testicular prostheses • Urethroplasty (reconstruction of female urethra) • Urethroplasty (reconstruction of male urethra) • Vaginectomy (removal of vagina) • Vaginoplasty (creation of vagina) • Vulvectomy (removal of vulva) Certain ancillary procedures, including but not limited to the following, are considered cosmetic and not medically necessary when performed as part of

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Gender Dysphoria Treatment (continued)	Jan. 1, 2023	specific benefit plan language may vary Supporting Information • Updated *Benefit Considerations*, *Clinical Evidence*, and *References* sections to reflect the most current information at the time of review	surgical treatment for Gender Dysphoria: Refer to the *Benefit Considerations* section of the policy as member specific benefit plan language may vary. Note: For fully insured group policies in New York, refer to the *Benefit Considerations* section for more information. • Abdominoplasty (also refer to the Medical Policy titled Panniculectomy and Body Contouring Procedures) • Blepharoplasty (also refer to the Medical Policy titled Brow Ptosis and Eyelid Repair) • Body contouring (e.g., fat transfer, lipoplasty, panniculectomy) (also refer to the Medical Policy titled Panniculectomy and Body Contouring Procedures) • Breast enlargement, including augmentation mammaplasty and breast implants* • Brow lift • Calf implants • Cheek, chin and nose implants • Injection of fillers or neurotoxins (also refer to the Medical Benefit Drug Policy titled Botulinum Toxins A and B) • Face/forehead lift and/or neck tightening • Facial bone remodeling for facial feminization • Laser or electrolysis hair removal not related to genital reconstruction • Hair transplantation • Lip augmentation • Lip reduction • Liposuction (suction-assisted lipectomy) (also refer to the Medical Policy titled Panniculectomy and Body Contouring Procedures) • Mastopexy • Pectoral implants for chest masculinization • Rhinoplasty (also refer to the Medical Policy titled Rhinoplasty and Other Nasal Surgeries) • Skin resurfacing (e.g., dermabrasion, chemical peels, laser) • Thyroid cartilage reduction/reduction thyroid chondroplasty/trachea shave (removal or reduction of the Adam's apple)*

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Gender Dysphoria Treatment (continued)	Jan. 1, 2023		• Voice modification surgery (e.g., laryngoplasty, glottoplasty or shortening of the vocal cords)* • Voice lessons and voice therapy* *Some plans may provide coverage for these services. Refer to the *Benefit Considerations* section of the policy as member specific benefit plan language may vary.

Provider Administered Drugs - Site of Care	Jan. 1, 2023	**Template Update**
		• Changed policy type classification from "Utilization Review Guideline" to "Medical Policy"
		Related Policies
		• Added reference link to the Medical Benefit Drug Policy titled:
		  ○ *RNA-Targeted Therapies (Amvuttra™ and Onpattro®)*
		  ○ *Skyrizi® (Risankizumab-Rzaa)*
		• Removed reference link to the Medical Benefit Drug Policy titled *Leqvio® (Inclisiran)*
		Coverage Rationale
		• Revised list of specialty medications that require healthcare provider administration:
		  ○ Added:
		  ▪ Amvuttra™ (vutrisiran)
		  ▪ Skyrizi® (Risankizumab-Rzaa)
		  ○ Removed Leqvio® (Inclisiran)
		Documentation Requirements
		• Updated list of specialty medications with associated documentation requirements:
			This policy addresses the criteria for consideration of allowing hospital outpatient facility specialty medication infusion services. This includes claim submission for hospital-based services with the following CMS/AMA Place of Service codes:
			• 19 Off Campus-Outpatient Hospital; and
			• 22 On Campus-Outpatient Hospital
			
			Alternative sites of care, such as non-hospital outpatient infusion, physician office, ambulatory infusion or home infusion services are well accepted places of service for medication infusion therapy. If an individual does not meet criteria for outpatient hospital facility infusion, alternative sites of care may be used.
			
			Outpatient hospital facility-based intravenous medication infusion is medically necessary for individuals who meet at least one of the following criteria (submission of medical records is required):
			• Documentation that the individual is medically unstable for administration of the prescribed medication at the alternative sites of care as determined by any of the following:
			  ○ The individual's complex medical status or therapy requires enhanced monitoring and potential intervention above and beyond the capabilities of the office or home infusion setting; or
			  ○ The individual's documented history of a significant comorbidity (e.g., cardiopulmonary disorder) or fluid overload status that precludes treatment at an alternative Site of Care; or
			  ○ Outpatient treatment in the home or office setting presents a health risk due to a clinically significant physical or cognitive impairment; or

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Provider Administered Drugs - Site of Care (continued)	Jan. 1, 2023	○ Added: ▪ Amvuttra™ (vutrisiran) (HCPCS code J0225) ▪ Skyrizi® (Risankizumab-Rzaa) (HCPCS code J2327) ○ Removed Leqvio® (Inclisiran) (HCPCS code J1306) **Applicable Codes** ● Added HCPCS codes J0225 and J2327 ● Removed HCPCS code J1306 **Supporting Information** ● Updated *References* section to reflect the most current information	○ Difficulty establishing and maintaining patent vascular access or ● Documentation (e.g., infusion records, medical records) of episodes of severe or potentially life-threatening adverse events (e.g., anaphylaxis, seizure, thromboembolism, myocardial infarction, renal failure) that have not been responsive to acetaminophen, steroids, diphenhydramine, fluids, infusion rate reductions, or other pre-medications, thereby increasing risk to the individual when administration is in the home or office setting; or ● Initial infusion or re-initiation of therapy after more than 6 months; or ● Homecare or infusion provider has deemed that the individual, home caregiver, or home environment is not suitable for home infusion therapy and both of the following: ○ The prescriber is unable to infuse in the office setting ○ There are no ambulatory infusion suite options available for this member Ongoing outpatient hospital facility-based infusion duration of therapy will be no more than 6 months to allow for reassessment of the individual's ability to receive therapy at an alternative Site of Care. This policy applies to these specialty medications that require healthcare provider administration: ● Actemra® (tocilizumab) ● Adakveo® (crizanlizumab-tmca) ● Aldurazyme® (laronidase) ● Amondys 45™ (casimersen) ● Amvuttra™ (vutrisiran) ● Apretude™ (cabotegravir) ● Aralast NP® (A1-PI) ● Avsola™ (infliximab-axxq) ● Benlysta® (belimumab) ● Cabenuva (cabotegravir; rilpiverine) ● Cerezyme® (imiglucerase)

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Provider Administered Drugs - Site of Care (continued)	Jan. 1, 2023		• Cimzia® (certolizumab pegol) • Cinqair® (reslizumab) • Crysvita® (burosumab-twza) • Elaprase® (idursulfase) • Elelyso® (taliglucerase) • Enjaymo™ (sutimlimab-jome) • Entyvio® (vedolizumab) • Evkeeza™ (evinacumab) • Exondys 51® (eteplirsen) • Fabrazyme® (agalsidase beta) • Fasenra® (benralizumab) • Givlaari® (givosiran) • Glassia® (A1-PI) • Ilaris® (canakinumab) • Ilumya™ (tildrakizumab-asmn) • Inflectra® (infliximab-dyyb) • Kanuma® (sebelipase alfa) • Lumizyme® (alglucosidase alfa) • Mepsevii™ (vestronidase alfa-vjbk) • Naglazyme® (galsulfase) • Nexviazyme™ (avalglucosidase alfa-ngpt) • Nucala® (mepolizumab) • Nulibry™ (fosdenopterin) • Onpattro® (patisiran) • Orencia® (abatacept) • Oxlumo™ (lumasiran) • Prolastin®-C™ (A1-PI) • Prolia® (denosumab) • Radicava® (edaravone) • Reblozyl® (luspatercept-aamt) • Remicade® (infliximab) • Revcovi® (elapegademase-lvlr) • Ryplazim® (plasminogen, human-tvmh)

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Provider Administered Drugs - Site of Care (continued)	Jan. 1, 2023		• Saphnelo™ (anifrolumab-fnia) • Simponi Aria® (golimumab) • Skyrizi® (risankizumab-rzaa) • Soliris® (eculizumab) • Stelara® (ustekinumab) • Tepezza® (teprotumumab-trbw) • Tezspire™ (tezepelumab-ekko) • Trogarzo® (ibalizumab-uiyk) • Ultomiris® (ravulizumab-cwvz) • Uplizna™ (inebilizumab-cdon) • Viltepso™ (viltolarsen) • Vimizim® (elosulfase alfa) • VPRIV® (velaglucerase) • Vyepti® (eptinezumab-jjmr) • Vyondys 53™ (golodirsen) • Vyvgart™ (efgartigimod) • Zemaira® (A1-PI)
Radiation Therapy: Fractionation, Image-guided Radiation Therapy, and Special Services	Jan. 1, 2023	Coverage Rationale *Radiation Therapy Fractionation* • Replaced language indicating: ○ "When providing external beam radiation therapy (EBRT) for the treatment of a bone metastasis the [listed services] are medically necessary" with "when providing *palliative* external beam radiation therapy (EBRT) for the treatment of a bone metastasis the [listed services] are medically necessary" ○ "When providing EBRT, with or without chemotherapy, for	**Radiation Therapy Fractionation** ***Bone Metastases*** When providing palliative external beam radiation therapy (EBRT) for the treatment of a bone metastasis the following are medically necessary: • Delivery of up to 10 fractions of radiation therapy • Delivery of greater than 10 fractions for the treatment of a site that has previously received radiation therapy ***Breast Adenocarcinoma*** When providing EBRT for breast adenocarcinoma the following are medically necessary: • Delivery of up to 21 fractions (inclusive of a boost to the tumor bed) • Delivery of up to 33 fractions (inclusive of a boost to the tumor bed) is medically necessary when any of the following criteria are met: ○ Treatment of supraclavicular and/or internal mammary lymph nodes; or

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Radiation Therapy: Fractionation, Image-guided Radiation Therapy, and Special Services (continued)	Jan. 1, 2023	locally advanced non-small cell lung cancer, delivery of greater than *30* fractions is not medically necessary" with "when providing EBRT, with or without chemotherapy, for locally advanced non-small cell lung cancer, delivery of greater than *35* fractions is not medically necessary" • Revised list of medically necessary services for: Bone Metastases ○ Removed "single fraction of radiation therapy" ○ Replaced "delivery of up to 10 fractions *for treatment of one of the following: a weight bearing bone such as femur, a bone that has previously undergone surgical stabilization, or spinal cord compression*" with "delivery of up to 10 fractions *of radiation therapy*" Locally Advanced Non-Small Cell Lung Cancer ○ Replaced "delivery of up to *30* fractions" with "delivery of up to *35* fractions" Prostate Adenocarcinoma ○ Removed "delivery of up to 45 fractions for localized prostate	○ Post-mastectomy radiation therapy; or ○ Individual has received previous thoracic radiation therapy ○ Individual has a connective tissue disorder such as lupus or scleroderma When providing EBRT for breast cancer, delivery of greater than 33 fractions (inclusive of a boost to the tumor bed) is not medically necessary. ***Locally Advanced Non-Small Cell Lung Cancer*** When providing (EBRT), with or without chemotherapy, for locally advanced non-small cell lung cancer the following is medical necessary: • Delivery of up to 35 fractions When providing EBRT, with or without chemotherapy, for locally advanced non-small cell lung cancer, delivery of greater than 35 fractions is not medically necessary. ***Prostate Adenocarcinoma*** When providing EBRT for prostate adenocarcinoma the following are medically necessary: • Delivery of up to 20 fractions for definitive treatment in an individual with Limited Metastatic Disease • Delivery of up to 28 fractions for localized prostate cancer • Delivery of up to 45 fractions for localized prostate cancer when any of the following criteria are met: ○ Individual with high-risk prostate cancer is undergoing radiation treatment to pelvic lymph nodes; or ○ Radiation therapy is delivered post-prostatectomy; or ○ Individual has a history of inflammatory bowel disease such as ulcerative colitis or Crohn's disease; or ○ Individual has received previous pelvic radiation therapy When providing EBRT for localized prostate cancer, delivery greater than 45

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Radiation Therapy: Fractionation, Image-guided Radiation Therapy, and Special Services (continued)	Jan. 1, 2023	cancer when EBRT is being delivered in combination with brachytherapy" *Image-Guided Radiation Therapy (IGRT)* • Replaced language indicating: ○ "When the criteria [listed in the policy] are not met, IGRT is not medically necessary to align bony landmarks without implanted fiducials" with "when the criteria [listed in the policy] are not met, IGRT is not medically necessary to align bony landmarks without implanted fiducials *(e.g., during palliative radiation therapy)*" ○ "Special services include the need for special dosimetry, special medical physics consultation, and special treatment procedure; refer to the *Coding Clarification* [section of the policy]" with "*for the use of IGRT for brachytherapy, SRS, SBRT, and* special services (*i.e.,* dosimetry, medical physics consultation, and treatment procedure), refer to the *Coding Clarification* [section of the policy]"	fractions is not medically necessary. **Image-Guided Radiation Therapy (IGRT)** Image guidance for radiation therapy is medically necessary under any of the following circumstances: • When used with intensity modulated radiation therapy (IMRT) (e.g. prostate cancer); or • When used with proton beam radiation therapy (PBRT); or • When the target has received prior radiation therapy or abuts previously irradiated area; or • When implanted fiducial markers are being used for target localization; or • During definitive treatment using 3D-CRT for the following: ○ Breast cancer and any of the following: ▪ Accelerated partial breast irradiation ▪ Breast boost with the use of photons ▪ Hypofractionated radiation therapy delivered over five fractions to the whole breast or chest wall ▪ Left breast cancer and deep inspiration breath hold (DIBH) technique is being used ▪ Patient is being treated in prone position ○ During boost treatment of rectal and bladder cancer ○ Esophageal cancer ○ Gastric cancer ○ Head and neck cancer ○ Hepatobiliary cancer ○ Lung cancer ○ Pancreatic cancer ○ Soft tissue sarcoma When the above criteria are not met, IGRT is not medically necessary including but not limited to any of the following circumstances: • Brachytherapy* • Stereotactic body radiation therapy (SBRT)**

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Radiation Therapy: Fractionation, Image-guided Radiation Therapy, and Special Services (continued)	Jan. 1, 2023	• Revised list of medically necessary indications: ○ Added: ▪ During definitive treatment using 3D-CRT for: – Breast cancer and any of the following: • Accelerated partial breast irradiation • Breast boost with the use of photons • Hypofractionated radiation therapy delivered over five fractions to the whole breast or chest wall • Left breast cancer and deep inspiration breath hold (DIBH) technique is being used • Patient is being treated in prone position – During boost treatment of rectal and bladder cancer – Gastric cancer – Hepatobiliary cancer	• Stereotactic radiosurgery (SRS)* * • Superficial treatment of skin cancer including superficial radiation therapy or electronic brachytherapy • To align bony landmarks without implanted fiducials (e.g. during palliative radiation therapy) Note: For the use of IGRT for brachytherapy, SRS, SBRT, and special services (i.e., dosimetry, medical physics consultation, and treatment procedure), refer to *Coding Clarification* section of the policy.

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Radiation Therapy: Fractionation, Image-guided Radiation Therapy, and Special Services (continued)	Jan. 1, 2023	– Lung cancer – Pancreatic cancer – Soft tissue sarcoma ○ Removed: ▪ For left sided breast cancer with the use of: – Deep inspiration breath hold (DIBH) technique – Prone technique ▪ During definitive treatment using 3D-CRT for: – Central nervous system tumors – Mediastinal tumors – Prostate cancer – Individuals who are severely obese (BMI ≥ 35) and are being treated for abdominal and pelvic tumors – Tumors with significant respiratory motion and motion assessment and management techniques are being utilized (e.g., 4D CT scan) ○ Replaced: ▪ "When used with intensity modulated radiation therapy (IMRT)" with	

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Radiation Therapy: Fractionation, Image-guided Radiation Therapy, and Special Services (continued)	Jan. 1, 2023	▪ "when used with intensity modulated radiation therapy (IMRT) *(e.g., prostate cancer)*" ▪ "*Primary* head and neck cancer" with "head and neck cancer" **Definitions** • Added definition of "Limited Metastatic Disease" **Applicable Codes** • Added notation to indicate IGRT codes should not be used for imaging performed during brachytherapy; verification of applicator position should be reported using simple simulation CPT code 77280 • Updated notation pertaining to special medical radiation physics consultation (CPT code 77370); replaced reference to "implanted *pacemaker or defibrillator* device" with "implanted *cardiac* devices" **Supporting Information** • Updated *Description of Services*, *Clinical Evidence*, and *References* sections to reflect the most current information	

Updated

Policy Title	Effective Date	Summary of Changes
Buprenorphine (Probuphine® & Sublocade®)	Dec. 1, 2022	**Coverage Rationale** • Replaced reference to "physician" with "provider" **Supporting Information** • Updated *Background*, *FDA*, and *References* sections to reflect the most current information
Somatostatin Analogs	Jan. 1, 2023	**Applicable Codes** • Added HCPCS code J1932 **Supporting Information** • Updated *References* section to reflect the most current information

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale

Ilumya™ (Tildrakizumab-Asmn)	Jan. 1, 2023	**Coverage Rationale**
		• Revised coverage criteria:
		  ○ Updated list of Janus kinase inhibitors the patient must not be receiving in combination with Ilumya; added "Rinvoq (upadacitinib)"
		• Revised medical necessity criteria for initial therapy:
		  ○ Updated list of biologic or targeted synthetic DMARDs FDA-approved for the treatment of plaque psoriasis with which the patient has previously been treated; added Enbrel (etanercept)
		  ○ Updated list of preferred biologic products to which the patient has a history of failure, contraindication, or intolerance; added Enbrel (etanercept)
		  ○ Updated list of Biologic DMARDs the patient must not be receiving in combination with Ilumya; added Enbrel (etanercept)
			Ilumya to be used as a self-administered, subcutaneous injection for the treatment of plaque psoriasis should be obtained under the pharmacy benefit.
			
			Ilumya (tildrakizumab) is proven for provider administration for the treatment of moderate to severe plaque psoriasis when the following criteria are met:
			• For initial therapy:
			  ○ Diagnosis of moderate to severe plaque psoriasis; and
			  ○ Physician attestation that the patient is unable to self-administer or there is no competent caregiver to administer the drug; physician must submit explanation; and
			  ○ Patient is not receiving Ilumya in combination with any of the following:
			  ▪ Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
			  ▪ Janus kinase inhibitor [e.g., Xeljanz (tofacitinib), Rinvoq (upadacitinib)]
			  ▪ Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]
			  and
			  ○ Dosing is in accordance with the United States Food and Drug

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Ilumya™ (Tildrakizumab-Asmn) (continued)	Jan. 1, 2023	Supporting Information • Updated *CMS* section to reflect the most current information	Administration approved labeling; and ○ Initial authorization will be for no longer than 12 months. • For continuation of therapy: ○ Documentation of positive clinical response to Ilumya therapy; and ○ Physician attestation that the patient is unable to self-administer or there is no competent caregiver to administer the drug; physician must submit explanation; and ○ Patient is not receiving Ilumya in combination with any of the following: ▪ Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)] ▪ Janus kinase inhibitor [e.g., Xeljanz (tofacitinib), Rinvoq (upadacitinib)] ▪ Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)] and ○ Dosing is in accordance with the United States Food and Drug Administration approved labeling; and ○ Reauthorization will be for no longer than 12 months. Ilumya (tildrakizumab) is medically necessary for provider administration for the treatment of moderate to severe plaque psoriasis when the following criteria are met: • For initial therapy, submission of medical records (e.g., chart notes, laboratory values) documenting all of the following: ○ Diagnosis of chronic moderate to severe plaque psoriasis; and ○ Greater than or equal to 3% body surface area involvement, palmoplantar, facial, genital involvement, or severe scalp psoriasis; and ○ One of the following: ▪ Both of the following: – History of failure, contraindication, or intolerance to one

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Ilumya™ (Tildrakizumab-Asmn) (continued)	Jan. 1, 2023		of the following topical therapies: • Corticosteroids (e.g., betamethasone, clobetasol, desonide) • Vitamin D analogs (e.g., calcitriol, calcipotriene) • Tazarotene • Calcineurin inhibitors (e.g., tacrolimus, pimecrolimus) • Anthralin • Coal tar and – History of failure to a 3 month trial of methotrexate at maximally indicated dose, unless contraindicated or clinically significant adverse effects are experienced or ▪ Patient has been previously treated with a biologic or targeted synthetic DMARD FDA-approved for the treatment of plaque psoriasis [e.g., Cimzia (certolizumab), Humira (adalimumab), Otezla (apremilast), Skyrizi (risankizumab-rzaa), Stelara (ustekinumab), Tremfya (guselkumab), Enbrel (etanercept)]. and ○ History of failure, contraindication, or intolerance to two of the following preferred biologic products *(for Medicare reviews, refer to the CMS section of the policy*)*: ▪ Humira (adalimumab) ▪ Stelara (ustekinumab) ▪ Tremfya (guselkumab) ▪ Cimzia (certolizumab) ▪ Skyrizi (risankizumab) ▪ Enbrel (etanercept) and ○ One of the following *(for Medicare reviews, refer to the CMS section of the policy*)*: ▪ History of a 6 month trial of Cosentyx (secukinumab) with moderate clinical response yet residual disease activity; or

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Ilumya™ (Tildrakizumab-Asmn) (continued)	Jan. 1, 2023		▪ Both of the following: – History of intolerance or adverse event to Cosentyx – Physician attests that in their clinical opinion the same intolerance or adverse event would not be expected to occur with Ilumya and ○ Physician attestation that the patient is unable to self-administer or there is no competent caregiver to administer the drug; physician must submit explanation; and ○ Patient is not receiving Ilumya in combination with any of the following: ▪ Biologic DMARD [e.g., Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab), Cosentyx (secukinumab), Orencia (abatacept), Enbrel (etanercept)] ▪ Janus kinase inhibitor [e.g., Xeljanz (tofacitinib), Rinvoq (upadacitinib)] ▪ Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)] and ○ Dosing is in accordance with the United States Food and Drug Administration approved labeling; and ○ Prescribed by or in consultation with a dermatologist; and ○ Initial authorization will be for no longer than 12 months. ● For continuation of therapy: ○ Documentation of positive clinical response to Ilumya therapy; and ○ Physician attestation that the patient is unable to self-administer or there is no competent caregiver to administer the drug. Physician must submit explanation; and ○ Patient is not receiving Ilumya in combination with any of the following: ▪ Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Ilumya™ (Tildrakizumab-Asmn) (continued)	Jan. 1, 2023		▪ Janus kinase inhibitor [e.g., Xeljanz (tofacitinib), Rinvoq (upadacitinib)] ▪ Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)] and ○ Dosing is in accordance with the United States Food and Drug Administration approved labeling; and ○ Reauthorization will be for no longer than 12 months.
Leqvio® (Inclisiran)	Jan. 1, 2023	**Related Policies** • Removed reference link to the Medical Policy titled *Provider Administered Drugs – Site of Care* **Coverage Rationale** • Revised coverage criteria: *Initial Therapy* ○ Added criterion to allow coverage when atherosclerotic cardiovascular disease (ASCVD) is confirmed by stable or unstable angina ○ Added criterion requiring: ▪ One of the following: – Patient has been receiving at least 12 consecutive weeks of high intensity statin therapy [i.e., atorvastatin 40-80 mg, rosuvastatin 20-40 mg] and will continue to receive a high intensity statin at maximally tolerated dose – Both of the following: • Patient is unable to tolerate high-intensity statin as evidenced by	Leqvio (inclisiran) is proven and medically necessary for the treatment of heterozygous familial hypercholesterolemia (HeFH) or clinical atherosclerotic cardiovascular disease (ASCVD) in patients who meet all of the following criteria: • For initial therapy, all of the following: ○ Diagnosis of one of the following: ▪ Heterozygous familial hypercholesterolemia (HeFH) as confirmed by one of the following: – Both of the following: • Pre-treatment LDL-C greater than or equal to 190 mg/dL (greater than or equal to 155 mg/dL if less than 16 years of age); and • One of the following: ○ Family history of myocardial infarction in first-degree relative < 60 years of age; or ○ Family history of myocardial infarction in second-degree relative < 50 years of age; or ○ Family history of LDL-C greater than or equal to 190 mg/dL in first- or second-degree relative; or ○ Family history of heterozygous or homozygous familial hypercholesterolemia in first- or second-degree relative; or ○ Family history of tendinous xanthomata and/or arcus cornealis in first- or second degree relative or

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Leqvio® (Inclisiran) (continued)	Jan. 1, 2023	one of the following intolerable and persistent (i.e., more than 2 weeks) symptoms: ○ Myalgia (muscle symptoms without CK elevations); or ○ Myositis (muscle symptoms with CK elevations < 10 times upper limit of normal [ULN]) • Patient has been receiving at least 12 consecutive weeks of low-intensity or moderate-intensity statin therapy [i.e., atorvastatin 10-20 mg, rosuvastatin 5-10 mg, simvastatin ≥ 10 mg, pravastatin ≥ 10 mg, lovastatin 20-40 mg, Lescol XL (fluvastatin XL) 80 mg, fluvastatin 20-40 mg up to 40mg twice daily or Livalo (pitavastatin) ≥ 1 mg] and will continue to receive a low-intensity or moderate-intensity statin at maximally tolerated dose – Patient is unable to tolerate low or moderate-, and high-	– Both of the following: • Pre-treatment LDL-C greater than or equal to 190 mg/dL (greater than or equal to 155 mg/dL if less than 16 years of age); and • One of the following: ○ Functional mutation in LDL, apoB, or PCSK9 gene; or ○ Tendinous xanthomata; or ○ Arcus cornealis before age 45 or ▪ Atherosclerotic cardiovascular disease (ASCVD) as confirmed by one of the following: – Acute coronary syndromes; or – History of myocardial infarction; or – Stable or unstable angina; or – Coronary or other arterial revascularization; or – Stroke; or – Transient ischemic attack; or – Peripheral arterial disease presumed to be of atherosclerotic origin and ○ One of the following: ▪ Patient has been receiving at least 12 consecutive weeks of high intensity statin therapy [i.e. atorvastatin 40-80 mg, rosuvastatin 20-40 mg] and will continue to receive a high intensity statin at maximally tolerated dose or ▪ Both of the following: – Patient is unable to tolerate high-intensity statin as evidenced by one of the following intolerable and persistent (i.e. more than 2 weeks) symptoms: • Myalgia (muscle symptoms without CK elevations); or • Myositis (muscle symptoms with CK elevations < 10

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Leqvio® (Inclisiran) (continued)	Jan. 1, 2023	intensity statins as evidenced by one of the following: • One of the following intolerable and persistent (i.e., more than 2 weeks) symptoms for low or moderate-, and high-intensity statins: ○ Myalgia (muscle symptoms without CK elevations); or ○ Myositis (muscle symptoms with CK elevations < 10 times upper limit of normal [ULN]) • Patient has a labeled contraindication to all statins • Patient has experienced rhabdomyolysis or muscle symptoms with statin treatment with CK elevations > 10 times ULN ▪ One of the following: – One of the following LDL-C values while on maximally tolerated lipid lowering therapy for a minimum of at least 12 weeks within the last 120 days or 120 days prior to starting Leqvio therapy:	times upper limit of normal [ULN]) and – Patient has been receiving at least 12 consecutive weeks of low-intensity or moderate-intensity statin therapy [i.e. atorvastatin 10-20 mg, rosuvastatin 5-10 mg, simvastatin ≥ 10 mg, pravastatin ≥ 10 mg, lovastatin 20-40 mg, Lescol XL (fluvastatin XL) 80 mg, fluvastatin 20-40 mg up to 40mg twice daily or Livalo (pitavastatin) ≥ 1 mg] and will continue to receive a low-intensity or moderate-intensity statin at maximally tolerated dose or ▪ Patient is unable to tolerate low or moderate-, and high-intensity statins as evidenced by one of the following: – One of the following intolerable and persistent (i.e. more than 2 weeks) symptoms for low or moderate-, and high-intensity statins: • Myalgia (muscle symptoms without CK elevations); or • Myositis (muscle symptoms with CK elevations < 10 times upper limit of normal [ULN]) or – Patient has a labeled contraindication to all statins or – Patient has experienced rhabdomyolysis or muscle symptoms with statin treatment with CK elevations > 10 times ULN and ○ One of the following: ▪ One of the following LDL-C values while on maximally tolerated lipid lowering therapy for a minimum of at least 12 weeks within the last 120 days or 120 days prior to starting Leqvio therapy: – LDL-C ≥ 100 mg/dL with ASCVD; or – LDL-C ≥ 130 mg/dL without ASCVD

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Leqvio® (Inclisiran) (continued)	Jan. 1, 2023	• LDL-C ≥ 100 mg/dL with ASCVD; or • LDL-C ≥ 130 mg/dL without ASCVD – Both of the following: • One of the following LDL-C values while on maximally tolerated lipid lowering therapy for a minimum of at least 12 weeks within the last 120 days or 120 days prior to starting Leqvio therapy: ○ LDL-C between 70 mg/dL and 99 mg/dL with ASCVD; or ○ LDL-C between 100 mg/dL and 129 mg/dL without ASCVD • One of the following: ○ Patient has been receiving at least 12 consecutive weeks of ezetimibe (Zetia®) therapy as adjunct to maximally tolerated statin therapy; or ○ Patient has a history of contraindication, or intolerance to ezetimibe	or ▪ Both of the following: – One of the following LDL-C values while on maximally tolerated lipid lowering therapy for a minimum of at least 12 weeks within the last 120 days or 120 days prior to starting Leqvio therapy: • LDL-C between 70 mg/dL and 99 mg/dL with ASCVD; or • LDL-C between 100 mg/dL and 129 mg/dL without ASCVD and – One of the following: • Patient has been receiving at least 12 consecutive weeks of ezetimibe (Zetia®) therapy as adjunct to maximally tolerated statin therapy; or • Patient has a history of contraindication, or intolerance to ezetimibe and ○ Used as an adjunct to a low-fat diet and exercise; and ○ Leqvio will not be used in combination with PCSK9 inhibitor therapy; and ○ Prescriber attests to the following: the information provided is true and accurate to the best of their knowledge and they understand that UnitedHealthcare may perform a routine audit and request the medical information necessary to verify the accuracy of the information provided; and ○ Leqvio dosing is in accordance with the United States Food and Drug Administration approved labeling; and ○ Initial authorization will be for no more than 12 months. • For continuation of therapy, all of the following: ○ Documentation of a positive clinical response to therapy from pre-treatment baseline (e.g., achieved LDL-C goal of < 100 mg/dL or achieved a 50% reduction in LDL-C levels); and

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Leqvio® (Inclisiran) (continued)	Jan. 1, 2023	▪ Used as an adjunct to a low-fat diet and exercise ▪ Prescriber attests the information provided is true and accurate to the best of their knowledge and they understand that UnitedHealthcare may perform a routine audit and request the medical information necessary to verify the accuracy of the information provided ○ Removed criterion requiring: ▪ Leqvio is prescribed by a lipid specialist (e.g., cardiologist, endocrinologist, lipid specialist/lipidologist) ▪ One of the following: – Despite adherence to PCSK9 therapy (defined by at least 12 consecutive weeks of use), one of the following: • Both of the following: ○ Patient has clinical ASCVD; and ○ Patient failed to achieve LDL-C goal of < 70 mg/dL • Both of the following: ○ Patient has severe heterozygous familial hypercholesterolemia (HeFH) (pre-treatment LDL-C ≥	○ Patient continues to receive statin at maximally tolerated dose (unless patient has an inability to take statins) in combination with Leqvio; and ○ Patient is continuing a low-fat diet and exercise regimen; and ○ Leqvio will not be used in combination with PCSK9 inhibitor therapy; and ○ Prescriber attests to the following: the information provided is true and accurate to the best of their knowledge and they understand that UnitedHealthcare may perform a routine audit and request the medical information necessary to verify the accuracy of the information provided; and ○ Leqvio dosing is in accordance with the United States Food and Drug Administration approved labeling; and ○ Reauthorization will be for no more than 12 months.

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Leqvio® (Inclisiran) (continued)	Jan. 1, 2023	190 mg/dL); and ○ Patient failed to achieve LDL-C goal of < 100 mg/dL – Patient has a history of intolerance or contraindication to PCSK9 therapy ▪ The patient will continue other traditional low-density lipoprotein-cholesterol (LDL-C) lowering therapies (e.g., maximally tolerated statins, ezetimibe) in combination with Leqvio *Continuation of Therapy* ○ Added criterion requiring: ▪ Patient is continuing a low-fat diet and exercise regimen ▪ Prescriber attests the information provided is true and accurate to the best of their knowledge and they understand that UnitedHealthcare may perform a routine audit and request the medical information necessary to verify the accuracy of the information provided ○ Replaced criterion requiring "the patient continues *treatment with other traditional low-density lipoprotein-cholesterol (LDL-C) lowering therapies (e.g., statin, ezetimibe)* in combination with Leqvio" with "the patient	

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Leqvio® (Inclisiran) (continued)	Jan. 1, 2023	continues *to receive statin at maximally tolerated dose (unless patient has an inability to take statins)* in combination with Leqvio" Supporting Information • Updated *CMS* section to reflect the most current information	
Maximum Dosage and Frequency	Jan. 1, 2023	Coverage Rationale • Revised list of appliable drug products; added: ○ Ranibizumab-nuna (Byooviz™) ○ Ranibizumab-eqrn (Cimerli™) *Maximum Allowed Quantities by HCPCS Units* • Updated HCPCS code for Alymsys (bevacizumab-maly) to reflect annual edits; replaced C9142 with Q5126 *Maximum Allowed Quantities for National Drug Code (NDC) Billing* • Revised quantity guidelines for Actemra (tocilizumab); removed: ○ How Supplied: ▪ 162 mg/0.9 mL pre-filled syringe ▪ 162 mg/0.9 mL pre-filled syringe autoinjector ○ NDCs: ▪ 50242-0138-01 ▪ 50242-0143-01 ○ Maximum Allowed: 0.9 mL *Maximum Allowed Frequencies* Actemra (tocilizumab) • Added language to indicate the maximum	This policy provides information about the maximum dosage per administration and dosing frequency for certain medications administered by a medical professional. Most medications have a maximum dosage and frequency based upon body surface area or patient weight or a set maximal dosage and frequency independent of patient body size. **Drug Products** • abatacept (Orencia®) • aflibercept (Eylea®) • atezolizumab (Tecentriq®) • avelumab (Bavencio®) • bevacizumab (Avastin®) • bevacizumab-awwb (Mvasi™) • bevacizumab-bvzr (Zirabev®) • bevacizumab-maly (Alymsys®) • brolucizumab-dbll (Beovu®) • cemiplimab-rwlc (Libtayo®) • certolizumab pegol (Cimzia®) • denosumab (Prolia® & Xgeva®) • durvalumab (Imfinzi®) • eculizumab (Soliris®) • emicizumab-kxwh (Hemlibra®) • golimumab (Simponi Aria®) • infliximab (Remicade®) • infliximab-axxq (Avsola™) • infliximab-dyyb (Inflectra®)

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Maximum Dosage and Frequency (continued)	Jan. 1, 2023	allowed frequency for the diagnosis of giant cell arteritis is administration once every 4 weeks **Byooviz (ranibizumab-nuna)** • Updated the maximum allowed frequency for the diagnosis of myopic choroidal neovascularization (mCNV); added language to indicate patients may be retreated, if needed, up to a maximum of 12 doses per year per eye **Cimerli (ranibizumab- eqrn) *(new to policy)*** • Added the maximum allowed frequency for the diagnosis of: ○ Myopic choroidal neovascularization (mCNV): ▪ The recommended dose is 0.5 mg to affected eye(s) once a month (approximately every 28 days) for up to 3 months ▪ Patients may be retreated if necessary ▪ Maximum of 12 doses per year per eye ○ Diabetic macular edema (DME) and diabetic retinopathy (DR): ▪ The recommended dose is 0.3 mg to affected eye(s) once a month (approximately every 28 days) ▪ Maximum of 12 doses per year per eye ○ Macular edema following retinal vein occlusion (RVO):	• infliximab-abda (Renflexis®) • ipilimumab (Yervoy®) • nivolumab (Opdivo®) • omalizumab (Xolair®) • patisiran (Onpattro®) • pegaptanib sodium (Macugen®) • pegfilgrastim (Neulasta®) • pegfilgrastim-apgf (Nyvepria™) • pegfilgrastim-cbqv (Udenyca®) • pegfilgrastim-jmdb (Fulphila™) • pegfilgrastim-bmez (Ziextenzo®) • pembrolizumab (Keytruda®) • ranibizumab (Lucentis®) • ranibizumab-nuna (Byooviz™) • ranibizumab-eqrn (Cimerli™) • ravulizumab-cwvz (Ultomiris®) • rituximab (Rituxan®) • rituximab-pvvr (Ruxience™) • rituximab-abbs (Truxima®) • rituximab-arrx (Riabni™) • rituximab and hyaluronidase (Rituxan Hycela®) • testosterone cypionate (Depo-Testosterone®) • testosterone enanthate • testosterone pellets (Testopel®) • testosterone undecanoate (Aveed®) • tildrakizumab-asmn (Ilumya™) • tocilizumab (Actemra®) • trastuzumab (Herceptin®) • trastuzumab-anns (Kanjinti™) • trastuzumab-dkst (Ogivri™) • trastuzumab-dttb (Ontruzant®) • trastuzumab-pkrb (Herzuma®) • trastuzumab-qyyp (Trazimera™)

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Maximum Dosage and Frequency (continued)	Jan. 1, 2023	▪ The recommended dose is 0.5 mg to affected eye(s) once a month (approximately every 28 days) ▪ Maximum of 12 doses per year per eye ○ Neovascular (wet) age-related macular degeneration (AMD): ▪ The recommended dose is 0.5 mg to affected eye(s) once a month (approximately every 28 days) ▪ Treatment may be reduced to 3 once monthly doses, followed by an average of 4 to 5 injections over the subsequent 9 months ▪ Maximum of 12 doses per year per eye **Cimzia (certolizumab pegol)** • Updated the maximum allowed frequency for the diagnoses of ankylosing spondylitis, axial spondyloarthritis, plaque psoriasis (BW ≤ 90 kg), psoriatic arthritis, and rheumatoid arthritis; replaced "administered initially, and at weeks 2, 4, then every other/every *2* weeks thereafter" with "administered initially, and at weeks 2, 4, then every other week or every *4* weeks thereafter" **Applicable Codes** • Removed NDCs 50242-0138-01 and 50242-0143-01 **Supporting Information**	• ustekinumab (Stelara®) • vedolizumab (Entyvio®) • zoledronic acid (zoledronic acid, Reclast®) The use of medications included in this policy when given within the maximum dosage and/or frequency based upon body surface area or patient weight or a set of maximal dosage and/or frequency independent of patient body size are proven when used according to labeled indications or when otherwise supported by published clinical evidence. The medications included in this policy when given beyond maximum dosages and/or frequency based upon body surface area or patient weight or a set maximal dosage independent of patient body size are not supported by package labeling or published clinical evidence and are unproven. This policy creates an upper dose limit based on the clinical evidence and the 95th percentile for adult body weight (140 kg) and body surface area (2.71 meters^2) in the U.S. (adult male, 30 to 39 years, Fryar, 2021). In some cases, the maximum allowed units and/or vials may exceed the upper level limit as defined within this policy due to an individual patient body weight > 140 kg or body surface area > 2.71 meters. Refer to the policy for complete details.

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Maximum Dosage and Frequency (continued)	Jan. 1, 2023	• Updated *References* section to reflect the most current information	

Oncology Medication Clinical Coverage	Jan. 1, 2023	**Coverage Rationale**
		• Revised list of UnitedHealthcare non-preferred oncology products; added "Vegzelma (bevacizumab-adcd)"
		Applicable Codes
		• Updated list of applicable HCPCS codes:
		  ○ Added A9607 and Q5126*
		  ○ Removed C9142*
		*(*annual edit)*
			Description
			This policy provides parameters for coverage of injectable oncology medications (including, but not limited to octreotide acetate, leuprolide acetate, leucovorin and levoleucovorin), including therapeutic radiopharmaceuticals, covered under the medical benefit based upon the National Comprehensive Cancer Network (NCCN) Drugs & Biologics Compendium® (NCCN Compendium®). The Compendium lists the appropriate drugs and biologics for specific cancers using US Food and Drug Administration (FDA)-approved disease indications and specific NCCN panel recommendations. Each recommendation is supported by a level of evidence category. Coverage of White Blood Cell Colony Stimulating Factors and Erythropoiesis-Stimulating Agents are addressed in separate policies. This policy does not provide coverage criteria for Chimeric Antigen Receptor (CAR)-T Cell products. Coverage determinations are based on the member's benefits and the OptumHealth Transplant Solutions criteria for covered transplants; refer to the Clinical Guideline titled Chimeric Antigen Receptor T-cell Therapy.
			Coverage Rationale
			Medical Necessity Plans
			The Oncology Products table below lists the UnitedHealthcare preferred oncology products and respective non-preferred products. Coverage will be provided for the UnitedHealthcare preferred oncology product contingent on the coverage criteria in the Diagnosis-Specific Criteria section.
			Coverage for any respective non-preferred oncology product will be provided contingent on the criteria in the Preferred Product Criteria and the Diagnosis-Specific Criteria sections. Members new to therapy will be

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Oncology Medication Clinical Coverage (continued)	Jan. 1, 2023		required to utilize the UnitedHealthcare preferred oncology product unless they meet the criteria in this section. ***Preferred Product Criteria*** *(For Medicare reviews, refer to the CMS section of the policy. * * *)* Treatment with the respective non-preferred product specified in the Oncology Products table below is medically necessary for oncology indications when both of the following are met: • History of intolerance or contraindication to one of the UnitedHealthcare's preferred oncology products; and • Physician attests that, in their clinical opinion, the same intolerance, contraindication, or adverse event would not be expected to occur with the respective non-preferred product. Oncology Products Below are UnitedHealthcare preferred oncology products with therapeutically equivalent and/or biosimilar* non-preferred products as determined by the UnitedHealthcare P&T Committee:

UnitedHealthcare Preferred Oncology Product	UnitedHealthcare Non-Preferred Oncology Product
Mvasi (bevacizumab-awwb)	Avastin (bevacizumab) Zirabev (bevacizumab-bvzr) Alymsys (bevacizumab-maly) Vegzelma (bevacizumab-adcd)
Kanjinti (trastuzumab-anns) Trazimera (trastuzumab-qyyp)	Herceptin (trastuzumab) Herceptin Hylecta (trastuzumab and hyaluronidase-oysk) Herzuma (trastuzumab-pkrb) Ogivri (trastuzumab-dkst) Ontruzant (trastuzumab-dttb)

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale	
Oncology Medication Clinical Coverage (continued)	Jan. 1, 2023		Kanjinti (trastuzumab-anns) + Perjeta (pertuzumab) Phesgo (pertuzumab, trastuzumab, hyaluronidase-zzxf)** Trazimera (trastuzumab-qyyp) + Perjeta (pertuzumab)	Herceptin (trastuzumab) + Perjeta (pertuzumab) Herceptin Hylecta (trastuzumab and hyaluronidase-oysk) + Perjeta (pertuzumab) Herzuma (trastuzumab-pkrb) + Perjeta (pertuzumab) Ogivri (trastuzumab-dkst) + Perjeta (pertuzumab) Ontruzant (trastuzumab-dttb) + Perjeta (pertuzumab)
			Ruxience (rituximab-pvvr) Truxima (rituximab-abbs)	Rituxan (rituximab) Rituxan Hycela (rituximab/hyaluronidase human, recombinant) Riabni (rituximab-arrx)
			Gemcitabine	Infugem (gemcitabine in sodium chloride injection)
			Leucovorin	Levoleucovorin
			Eligard, Lupron Depot 7.5 mg (J9217)	Lupron Depot 3.75 mg (J1950)

*Biosimilar means that the biological product is FDA-approved based on data demonstrating that it is highly similar to an already FDA-approved biological product, known as a reference product, and that there are no clinically meaningful differences between the biosimilar product and the reference product.

**Phesgo is a combination product of pertuzumab + trastuzumab.

Diagnosis-Specific Criteria

Injectable Oncology Medications

UnitedHealthcare recognizes indications and uses of injectable oncology

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Oncology Medication Clinical Coverage (continued)	Jan. 1, 2023		medications, including therapeutic radiopharmaceuticals, listed in the NCCN Drugs and Biologics Compendium with Categories of Evidence and Consensus of 1, 2A, and 2B as proven and medically necessary, and Categories of Evidence and Consensus of 3 as unproven and not medically necessary. UnitedHealthcare will cover all chemotherapy agents for individuals under the age of 19 years for oncology indications. The majority of pediatric patients receive treatments on national pediatric protocols that are quite similar in concept to the NCCN patient care guidelines. Refer to Preferred Product Criteria for the UnitedHealthcare preferred oncology products that have therapeutically equivalent and/or biosimilar products available.
RNA-Targeted Therapies (Amvuttra™ and Onpattro®)	Jan. 1, 2023	Coverage Rationale • Removed reference link to the Medical Benefit Drug Policy titled *Review at Launch for New to Market Medications* for Amvuttra (vutrisiran) • Revised coverage criteria for: *Amvuttra (vutrisiran)* ○ Updated list of medications the patient must not be receiving in combination with Amvuttra; replaced "*oligonucleotide* agents [e.g., Tegsedi (inotersen)], Vyndaqel (tafamidis meglumine), Vyndamax (tafamidis), or Onpattro (patisiran)" with "*RNA interference* agents [e.g., Onpattro (patisiran), Tegsedi (inotersen)] or *transthyretin stabilizers* [e.g., Vyndaqel (tafamidis meglumine) or Vyndamax (tafamidis)]"	Amvuttra (vutrisiran) and Onpattro (patisiran) are proven for the treatment of the polyneuropathy of hereditary transthyretin-mediated (hATTR) amyloidosis. Amvuttra (vutrisiran) is medically necessary for the treatment of the polyneuropathy of hATTR amyloidosis in patients who meet all of the following criteria: • For initial therapy, all of the following: ○ Both of the following: ▪ Diagnosis of hATTR amyloidosis with polyneuropathy ▪ Documentation that the patient has a pathogenic TTR mutation (e.g., V30M) and ○ Documentation of one of the following: ▪ Patient has a baseline polyneuropathy disability (PND) score ≤ IIIb ▪ Patient has a baseline familial amyloid polyneuropathy (FAP) Stage 1 or 2 ▪ Patient has a baseline neuropathy impairment score (NIS) ≥

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
RNA-Targeted Therapies (Amvuttra™ and Onpattro®) (continued)	Jan. 1, 2023	**Initial Therapy** ○ Added criterion to allow coverage when the patient has a baseline Karnofsky performance status (KPS) score ≥ 60% ○ Replaced criterion allowing coverage when "the patient has a baseline neuropathy impairment score (NIS) ≥ *5* and ≤ 130" with "the patient has a baseline neuropathy impairment score (NIS) ≥ *10* and ≤ 130" **Continuation of Therapy** ○ Added criterion to allow coverage when the patient continues to have a KPS score of ≥ 60% ○ Replaced criterion allowing coverage when "the patient continues to have a neuropathy impairment score (NIS) ≥ *5* and ≤ 130" with "the patient continues to have a neuropathy impairment score (NIS) ≥ *10* and ≤ 130" ***Onpattro (patisiran)*** ○ Updated list of medications the patient must not be receiving in combination with Onpattro; replaced "*oligonucleotide* agents [e.g., Tegsedi (inotersen)], Vyndaqel (tafamidis meglumine), Vyndamax (tafamidis), or Amvuttra (vutrisiran)" with "*RNA interference* agents [e.g., Amvuttra (vutrisiran), Tegsedi (inotersen)] or *transthyretin stabilizers* [e.g., Vyndaqel	10 and ≤ 130 ▪ Patient has a baseline Karnofsky performance status (KPS) score ≥ 60% and ○ Presence of clinical signs and symptoms of the disease (e.g., peripheral sensorimotor polyneuropathy, autonomic neuropathy, motor disability, etc.); and ○ Patient has not had a liver transplant; and ○ Patient is not receiving Amvuttra in combination with any of the following: ▪ RNA interference agents [e.g., Onpattro (patisiran), Tegsedi (inotersen)] ▪ Transthyretin stabilizers [e.g., Vyndaqel (tafamidis meglumine) or Vyndamax (tafamidis)] and ○ Prescribed by or in consultation with a neurologist; and ○ Dosing is in accordance with the US Food and Drug Administration prescribing information; and ○ Initial authorization is for no more than 12 months. • For continuation of therapy, all of the following: ○ Patient has previously received treatment with Amvuttra and ○ Documentation of one of the following: ▪ Patient continues to have a PND score ≤ IIIb ▪ Patient continues to have a FAP stage 1 or 2 ▪ Patient continues to have a NIS score ≥ 10 and ≤ 130 ▪ Patient continues to have a KPS score ≥ 60% and ○ Documentation that the patient has experienced a positive clinical response to Amvuttra (e.g., improved neurologic impairment, motor function, quality of life, slowing of disease progression, etc.); and ○ Patient is not receiving Amvuttra in combination with any of the

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
RNA-Targeted Therapies (Amvuttra™ and Onpattro®) (continued)	Jan. 1, 2023	(tafamidis meglumine) or Vyndamax (tafamidis)]" **Applicable Codes** • Updated list of applicable HCPCS codes to reflect annual edits; replaced C9399, J3490, and J3590 with J0225	following: ▪ RNA interference agents [e.g., Onpattro (patisiran), Tegsedi (inotersen)] ▪ Transthyretin stabilizers [e.g., Vyndaqel (tafamidis meglumine) or Vyndamax (tafamidis)] and ○ Prescribed by or in consultation with a neurologist; and ○ Dosing is in accordance with the US Food and Drug Administration prescribing information; and ○ Authorization is for no more than 12 months. Onpattro (patisiran) are medically necessary for the treatment of the polyneuropathy of hATTR amyloidosis in patients who meet all of the following criteria: • For initial therapy, all of the following: ○ Both of the following: ▪ Diagnosis of hATTR amyloidosis with polyneuropathy ▪ Documentation that the patient has a pathogenic TTR mutation (e.g., V30M) and ○ Documentation of one of the following: ▪ Patient has a baseline polyneuropathy disability (PND) score ≤ IIIb ▪ Patient has a baseline familial amyloid polyneuropathy (FAP) Stage 1 or 2 ▪ Patient has a baseline neuropathy impairment score (NIS) ≥ 5 and ≤ 130 and ○ Presence of clinical signs and symptoms of the disease (e.g., peripheral sensorimotor polyneuropathy, autonomic neuropathy, motor disability, etc.); and ○ Patient has not had a liver transplant; and ○ Patient is not receiving Onpattro in combination with any of the

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RNA-Targeted Therapies (Amvuttra™ and Onpattro®) (continued)	Jan. 1, 2023		following: ▪ RNA interference agents [e.g., Amvuttra (vutrisiran), Tegsedi (inotersen)]] ▪ Transthyretin stabilizers [e.g., Vyndaqel (tafamidis meglumine) or Vyndamax (tafamidis)] and ○ Prescribed by or in consultation with a neurologist; and ○ Dosing is in accordance with the US Food and Drug Administration prescribing information; and ○ Initial authorization is for no more than 12 months. ● For continuation of therapy, all of the following: ○ Patient has previously received treatment with Onpattro; and ○ Documentation of one of the following: ▪ Patient continues to have a PND score ≤ IIIb ▪ Patient continues to have a FAP Stage 1 or 2 ▪ Patient continues to have a NIS score ≥ 5 and ≤ 130 and ○ Documentation that the patient has experienced a positive clinical response to requested drug (e.g., improved neurologic impairment, motor function, quality of life, slowing of disease progression, etc.); and ○ Patient is not receiving Onpattro in combination with any of the following: ▪ RNA interference agents [e.g., Amvuttra (vutrisiran), Tegsedi (inotersen)] ▪ Transthyretin stabilizers [e.g., Vyndaqel (tafamidis meglumine) or Vyndamax (tafamidis)] and ○ Prescribed by or in consultation with a neurologist; and ○ Dosing is in accordance with the US Food and Drug Administration prescribing information; and ○ Authorization is for no more than 12 months. Onpattro (patisiran) is unproven and not medically necessary for the

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RNA-Targeted Therapies (Amvuttra™ and Onpattro®) (continued)	Jan. 1, 2023		treatment of: • Sensorimotor or autonomic neuropathy not related to hATTR amyloidosis • Primary or leptomeningeal amyloidosis
Tezspire® (Tezepelumab-Ekko)	Jan. 1, 2023	Coverage Rationale • Revised medical necessity criteria for initial therapy; added criterion to allow coverage when the patient's asthma is not of the eosinophilic, allergic, or oral corticosteroid dependent phenotype	Tezspire is proven for add-on maintenance treatment for patients that meet the following criteria: • For initial therapy, both of the following: ○ Diagnosis of severe asthma; and ○ Will be used as add-on maintenance therapy ○ Dosing is in accordance with the United States Food and Drug Administration approved labeling; and ○ Initial authorization will be for no more than 6 months. • For continuation of therapy, all of the following: ○ Documentation of positive clinical response; and ○ Used in combination with an inhaled corticosteroid (ICS)-containing controller medication; and ○ Patient is not receiving Tezspire in combination with any of the following: ▪ Anti-interleukin 5 therapy [e.g., Cinqair (reslizumab), Fasenra (benralizumab), Nucala (mepolizumab] ▪ Anti-IgE therapy [e.g., Xolair (omalizumab)] ▪ Anti-interleukin 4 therapy [e.g., Dupixent (dupilumab)] and ○ Dosing is in accordance with the United States Food and Drug Administration approved labeling; and ○ Reauthorization will be for no more than 12 months. Tezspire is medically necessary when all of the following criteria is met: • For initial therapy, all of the following: ○ Diagnosis of severe asthma; and ○ Classification of asthma as uncontrolled or inadequately controlled as defined by at least one of the following: ▪ Poor symptom control (e.g., ACQ score consistently greater

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Tezspire® (Tezepelumab-Ekko) (continued)	Jan. 1, 2023		than 1.5 or ACT score consistently less than 20); or ▪ Two or more bursts of systemic corticosteroids for at least 3 days each in the previous 12 months; or ▪ Asthma-related emergency treatment (e.g., emergency room visit, hospital admission, or unscheduled physician's office visit for nebulizer or other urgent treatment); or ▪ Airflow limitation (e.g., after appropriate bronchodilator withhold FEV1 less than 80% predicted (in the face of reduced FEV1/FVC defined as less than the lower limit of normal); or ▪ Patient is currently dependent on maintenance therapy with oral corticosteroids for the treatment of asthma and ○ Used in combination with one of the following: ▪ One maximally-dosed (appropriately adjusted for age) combination inhaled corticosteroid (ICS)/long-acting beta$_2$ agonist (LABA) product [e.g., Advair/AirDuo Respiclick (fluticasone propionate/salmeterol), Symbicort (budesonide/formoterol), Breo Ellipta (fluticasone furoate/vilanterol)]; or ▪ Combination therapy including both of the following: – One high-dose (appropriately adjusted for age) ICS product [e.g., ciclesonide (Alvesco®), mometasone furoate (Asmanex®), beclomethasone dipropionate (QVAR®)]; and – One additional asthma controller medication [e.g., LABA - olodaterol (Striverdi®) or indacaterol (Arcapta®), leukotriene receptor antagonist – montelukast (Singulair®), theophylline] and ○ One of the following (for Medicare reviews, refer to the CMS section of the policy*): ○ Both of the following:

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Tezspire® (Tezepelumab-Ekko) (continued)	Jan. 1, 2023		– Tezspire will be used to treat eosinophilic asthma; and – History of failure, contraindication, or intolerance to a 4-month trial of both of the following: • Anti-interleukin 5 therapy [e.g., Nucala (mepolizumab), Fasenra (benralizumab)] • Anti-interleukin 4 [e.g., Dupixent (dupilumab)]; or ○ Both of the following: – Tezspire will be used to treat persistent allergic asthma; and – History of failure, contraindication, or intolerance to a 4-month trial of Xolair (omalizumab); or ○ Both of the following: – Tezspire will be used to treat oral corticosteroid dependent asthma; and – History of failure, contraindication, or intolerance to a 4-month trial of Dupixent (duplimab); or ○ Patient's asthma is not of the eosinophilic, allergic or oral corticosteroid dependent phenotype; or ○ Patient is currently on Tezspire and ○ Patient is not receiving Tezspire in combination with any of the following: ▪ Anti-interleukin 5 therapy [e.g., Cinqair (reslizumab), Fasenra (benralizumab), Nucala (mepolizumab] ▪ Anti-IgE therapy [e.g., Xolair (omalizumab)] ▪ Anti-interleukin 4 therapy [e.g., Dupixent (dupilumab)] ○ Tezspire dosing is in accordance with the United States Food and Drug Administration approved labeling; and ○ Tezspire is prescribed by a pulmonologist or allergist/immunologist; and ○ Initial authorization will be for no more than 6 months. • For continuation of therapy, all of the following: ○ Documentation of a positive clinical response as demonstrated by

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Tezspire® (Tezepelumab-Ekko) (continued)	Jan. 1, 2023		at least one of the following: ▪ Reduction in the frequency of exacerbations ▪ Decreased utilization of rescue medications ▪ Increase in percent predicted FEV1 from pretreatment baseline ▪ Reduction in severity or frequency of asthma-related symptoms (e.g., wheezing, shortness of breath, coughing, etc.) and ○ Used in combination with an ICS-containing controller medication; and ○ Patient is not receiving Tezspire in combination with any of the following: ▪ Anti-interleukin 5 therapy [e.g., Cinqair (reslizumab), Fasenra (benralizumab), Nucala (mepolizumab] ▪ Anti-IgE therapy [e.g., Xolair (omalizumab)] ▪ Anti-interleukin 4 therapy [e.g., Dupixent (dupilumab)] and ○ Tezspire dosing is in accordance with the United States Food and Drug Administration approved labeling; and ○ Reauthorization will be for no more than 12 months.

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Durable Medical Equipment, Orthotics, Medical Supplies and Repairs/Replacements	Jan. 1, 2023	Coverage Rationale
		Medical Supplies
		• Added language to indicate:
		  ○ There are benefits for External Urinary Catheters for incontinence or retention
		  ○ Quantity limits may apply [to medical supplies]
		Coverage Limitations and Exclusions
		• Removed language indicating urinary catheters are excluded from coverage unless specifically stated as covered
		Definitions
		• Added definition of "External Urinary Catheter"
		Supporting Information
		• Updated *References* section to reflect the most current information

Preventive Care Services	Jan. 1, 2023	Frequently Asked Questions (FAQ)
		• Removed FAQ #14 pertaining to maternal depression screening
		Applicable Codes
		Preventive Care Services
		Hepatitis B Virus Infection Screening
		• Updated service description; added Jul. 2022 Bright Futures guideline to indicate Bright Futures recommends screening between the ages 0-21 years [perform risk assessment for hepatitis B virus (HBV) infection]
		• Updated lists of applicable codes; added:
		  ○ CPT code 87467
		  ○ ICD-10 diagnosis codes Z00.121 and Z00.129
		Statin Use for the Primary Prevention of Cardiovascular Disease in Adults - Cholesterol Screening (Lipid Disorders Screening)
		• Updated service description:
		  ○ Removed Nov. 2016 USPSTF rating "B"
		  ○ Added Aug. 2022 USPSTF rating "B" to indicate the USPSTF recommends clinicians prescribe a statin for the primary prevention of CVD for adults aged 40 to 75 years who have 1 or more CVD risk factor (i.e., dyslipidemia, diabetes, hypertension, or smoking) and an estimated 10-year risk of a cardiovascular event of 10% or greater
		Colorectal Cancer Screening
		• Updated list of applicable CPT codes *Code Group 5: Pre-Op/Consultation* to reflect annual edits; removed 99241
		Screening for Depression in Adults

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Preventive Care Services (continued)	Jan. 1, 2023	• Updated list of applicable CPT codes; added 96161
		• Updated preventive benefit instructions; added language to indicate the diagnosis codes listed for this service are not required for CPT code 96161
		Depression in Children and Adolescents (Screening)
		• Updated service description:
		  ○ Removed Feb. 2016 USPSTF "B" rating
		  ○ Added Oct. 2022 USPSTF "B" rating to indicate the USPSTF recommends screening for major depressive disorder (MDD) in adolescents aged 12-18 years
		• Updated list of applicable CPT codes; added 96161
		• Updated preventive benefit instructions; added language to indicate the diagnosis codes listed for this service are not required for CPT code 96161
		Screening for Anxiety in Children and Adolescents *(new to policy)*
		• Added service description for the Oct. 2022 USPSTF "B" rating to indicate the USPSTF recommends screening for anxiety in children and adolescents aged 8 to 18 years
		• Added instruction to refer to the *Screening for Anxiety (HRSA)*, *Screening for Depression in Adults (USPSTF)*, *Perinatal Depression – Preventive Interventions (Counseling) (USPSTF)*, and *Depression and Suicide Risk Screening (Bright Futures)* sections of the policy for additional information
		• Added CPT code 96127
		• Added ICD-10 diagnosis code Z13.39
		• Added preventive benefit instruction to indicate CPT code 96127 requires diagnosis code Z13.39
		Fluoride Application in Primary Care
		• Updated service description:
		  ○ Removed Apr. 2017 Bright Futures guideline
		  ○ Added Jul. 2022 Bright Futures guideline to indicate Bright Futures adopted the May 2014 recommendation of the USPSTF and further recommends, once teeth are present, [to] apply fluoride varnish to all children every 3 to 6 months in the primary care or dental office, based on caries risk
		Behavioral/Social/Emotional Screening (Bright Futures)
		• Updated service description:
		  ○ Removed Apr. 2017 Bright Futures guideline
		  ○ Added Jul. 2022 Bright Futures guideline to indicate Bright Futures recommends behavioral/social/emotional screening annually from newborn to 21 years
		• Added instruction to refer to the *Screening for Anxiety (HRSA)*, *Screening for Depression in Adults (USPSTF)*, *Perinatal*

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Policy Title	Effective Date	Summary of Changes

Preventive Care Services (continued)	Jan. 1, 2023	*Depression – Preventive Interventions (Counseling) (USPSTF)*, and *Depression and Suicide Risk Screening (Bright Futures)* sections of the policy for additional information
		Depression and Suicide Risk Screening (Bright Futures)
		• Updated service description:
		  ○ Removed Apr. 2017 Bright Futures guideline
		  ○ Added Jul. 2022 Bright Futures guideline to indicate Bright Futures recommends screening adolescents age 12-21 years for depression and suicide risk, making every effort to preserve confidentiality of the adolescent
		Sudden Cardiac Arrest (SCA) and Sudden Cardiac Death (SCD) – Risk Assessment and ECG Screening (Bright Futures) *(new to policy)*
		• Added service description for the Jul. 2022 Bright Futures guideline to indicate Bright Futures recommends all children should be evaluated for conditions predisposing to SCA and SCD in the course of routine health care:
		  ○ A thorough and detailed history, family history, and physical examination are necessary to begin assessing SCA and SCD risk
		  ○ The ECG should be the first test ordered when there is a concern for SCA risk
		  ○ The ECG should be interpreted by a physician trained in recognizing electrical heart disease (i.e., a pediatric cardiologist or pediatric electrophysiologist)
		• Added lists of applicable codes:
		  ○ Added CPT codes 93000, 93005, and 93010
		  ○ Added ICD-10 diagnosis codes for:
		  ▪ At least one required for screening:
		  – Adult: Z00.00 and Z00.01
		  – Child: Z00.121 and Z00.129
		  ▪ Additional (at least one) required: I42.0, I42.1, I42.2, I45.81, I49.8, I49.9, R55, R06.00, R06.09, R53.83, R00.2, R01.0, R01.1, R03.0, Q87.40, Q87.410, Q87.418, Q87.42, Q87.43, Z82.41, Z84.81, and Z82.49
		• Added language to indicate a risk assessment is included in the code for a wellness examination visit; refer to the codes in the *Wellness Examinations* section of the policy
		• Added preventive benefit instructions to indicate ECG screening for those at risk:
		  ○ Is limited to ages 11 years to 21 years (ends on 22nd birthday)
		  ○ Requires one of the screening diagnosis codes and one of the additional diagnosis codes listed for this service
		Preventive Vaccines (Immunizations)
		Pneumococcal Conjugate
		• Revised language to indicate CPT code 90671 applies to both pediatric and adult age groups (no age benefit limit)

Coverage Determination Guideline Updates

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Policy Title	Effective Date	Summary of Changes

Preventive Care Services (continued)	Jan. 1, 2023	**Measles, Mumps, Rubella (MMR)**
		• Revised list of trade names associated with CPT code 90707; added "Priorix®"
		Expanded Women's Preventive Health
		Well-Woman Preventive Visits
		• Replaced references to "prenatal care" with "prenatal care *(antepartum)*"
		• Added CPT code 59430 for postpartum care visits (outpatient)
		• Added preventive benefit instruction to indicate:
		  ○ CPT code 99078 requires a pregnancy diagnosis code listed in the policy
		  ○ Postpartum care visits (outpatient) do not have diagnosis code requirements for the preventive benefit to apply
		Contraceptive Methods (Including Sterilizations)
		• Added service notation to indicate coverage includes member reimbursement for the cost of FDA-approved, cleared, or granted mobile device applications for use as contraception consistent with the FDA-approved, cleared, or granted indication
		• Added lists of applicable codes for *Code Group 7* for:
		  ○ *Related Visits: Related Evaluation and Management Office/Outpatient Visits for Contraception or Sterilization*: Added CPT/HCPCS codes 99202, 99203, 99204, 99205, 99211, 99212, 99213, 99214, 99215, 99417, and G0463
		  ○ *Related Pregnancy Tests: Pregnancy Tests When Related to Contraception or Sterilization*: Added CPT codes 81025, 84702, and 84703
		  ○ *Tubal Ligation Status*: Added ICD-10 diagnosis code Z98.51
		  ○ *Sterilization*: Added ICD-10 diagnosis code Z30.2
		  ○ *Contraceptive Management*: Added ICD-10 diagnosis codes Z30.012, Z30.013, Z30.014, Z30.017, Z30.018, Z30.019, Z30.09, Z30.40, Z30.42, Z30.430, Z30.431, Z30.432, Z30.433, Z30.46, Z30.49, Z30.8, and Z30.9
		• Added instruction to refer to the coding in the *Wellness Examinations* section of the policy
		• Added preventive benefit instructions to indicate the CPT codes in *Code Group 7* require one of the *Code Group 7* diagnosis codes
		Breastfeeding Services and Supplies
		• Updated list of applicable CPT codes to reflect annual edits; removed 99241 and 99343

General Information

The inclusion of a health service (e.g., test, drug, device or procedure) in this bulletin indicates only that UnitedHealthcare is adopting a new policy and/or updated, revised, replaced or retired an existing policy; it does not imply that UnitedHealthcare provides coverage for the health service. Note that most benefit plan documents exclude from benefit coverage health services identified as investigational or unproven/not medically necessary. Physicians and other health care professionals may not seek or collect payment from a member for services not covered by the applicable benefit plan unless first obtaining the member's written consent, acknowledging that the service is not covered by the benefit plan and that they will be billed directly for the service.

Note: The absence of a policy does not automatically indicate or imply coverage. As always, coverage for a health service must be determined in accordance with the member's benefit plan and any applicable federal or state regulatory requirements. Additionally, UnitedHealthcare reserves the right to review the clinical evidence supporting the safety and effectiveness of a medical technology prior to rendering a coverage determination.

UnitedHealthcare respects the expertise of the physicians, health care professionals, and their staff who participate in our network. Our goal is to support you and your patients in making the most informed decisions regarding the choice of quality and cost-effective care, and to support practice staff with a simple and predictable administrative experience. The Medical Policy Update Bulletin was developed to share important information regarding UnitedHealthcare Medical Policy, Medical Benefit Drug Policy, Coverage Determination Guideline, and Utilization Review Guideline updates. When information in this bulletin conflicts with applicable state and/or federal law, UnitedHealthcare follows such applicable federal and/or state law.

Policy Update Classifications

New

New clinical coverage criteria have been adopted for a health service (e.g., test, drug, device or procedure)

Updated

An existing policy has been reviewed and changes have not been made to the clinical coverage criteria; however, items such as the clinical evidence, FDA information, and/or list(s) of applicable codes may have been updated

Revised

An existing policy has been reviewed and revisions have been made to the clinical coverage criteria

Replaced

An existing policy has been replaced with a new or different policy

Retired

The health service(s) addressed in the policy are no longer being managed or are considered to be proven/medically necessary and are therefore not excluded as unproven/not medically necessary services, unless coverage guidelines or criteria are otherwise documented in another policy

The complete library of UnitedHealthcare Medical Policies, Medical Benefit Drug Policies, Coverage Determination Guidelines, and Utilization Review Guidelines is available at UHCprovider.com > Policies and Protocols > Commercial Policies > Medical & Drug Policies and Coverage Determination Guidelines.