



Centers for Medicare & Medicaid Services (CMS) Healthcare Common Procedure Coding System (HCPCS) Application Summaries and Coding Decisions Third Quarter 2021 Coding Cycle for Drug and Biological Products

This document presents a summary of each HCPCS code application and CMS' coding decision for each application processed in CMS' Third Quarter 2021 Drug and Biological HCPCS code application review cycle. Each summary includes:

- Application number;
- Topic/Issue;
- Summary of the applicant's request as written by the applicant with occasional non-substantive editorial changes made by CMS;
- CMS' final or preliminary coding decision; and
- Effective date of any coding action which, for the purpose of this publication, refers to the date the code is first available to be billed on claims.

The HCPCS coding decisions below will also be included in the January 2022 HCPCS Quarterly Update, pending publication by CMS in the coming weeks at:

<https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/HCPCS-Quarterly-Update>

For inquiries regarding coverage, please contact to the insurer(s) in whose jurisdiction(s) claim(s) would be filed. Specifically, contact the Medicaid agency in the state in which a Medicaid claim is filed, the individual private insurance entity, the Department of Veterans Affairs, or, for local Medicare coverage determinations, contact the Medicare contractor in the jurisdiction the claim would be filed. For detailed information describing CMS' national coverage determination process, refer to information published at <https://www.cms.gov/Medicare/Coverage/DeterminationProcess> and <https://www.cms.gov/Center/Special-Topic/Medicare-Coverage-Center>.

CYGNUS MATRIX- HCP2108043BTT4

Topic/Issue

Request to establish a new HCPCS Level II code to identify CYGNUS Matrix.

Applicant's suggested language: Q4XXX Cygnus Matrix, per square centimeter.

Applicant's Summary

CYGNUS Matrix is a multilayer allograft derived from the amnion and chorion layers of the placental membrane and is manufactured using our proprietary Integrity Processing™ Methodology, which helps to maintain the inherent levels of key extracellular matrices, including proteins, carbohydrates, growth factors, and cytokines. CYGNUS Matrix retains the structural and functional characteristics of the membrane to provide a barrier or covering, protecting injured tissue from the external environment. The multi-layer CYGNUS Matrix amniotic membrane allograft, ~400µm (0.4mm) thick, is up to 4X thicker than the single amnion layer amniotic membrane allografts which enhances the ability to meet clinical needs and allow use throughout the course of complex wound and burn repairs. CYGNUS Matrix is available in square and circular shapes, which reduces the associated potential to waste tissue. CYGNUS Matrix is shipped in a single use package with one unit per package and may be stored at ambient conditions for up to 5 years; it is prescribed by health care professionals.

Final Decision

Based on written feedback from the Food and Drug Administration's (FDA's) Tissue Reference Group (TRG), CYGNUS Matrix for "use as a wound covering or barrier in surgical, orthopedic, ophthalmic and wound applications," appears to be regulated solely under section 361 of the Public Health Service Act and the regulations in 21 CFR part 1271. As a result of our review of the TRG's feedback, CMS has decided to:

Establish new HCPCS Level II code Q4199 "Cygnus matrix, per square centimeter"

Effective: 1/1/2022

RYBREVANT- HCP210803VFML6

Topic/Issue

Request to establish a new HCPCS Level II code to identify Rybrevant.

Applicant's suggested language: JXXXX –amivantamab-vmjw 350 mg/7 mL (50 mg/mL) injection.

Applicant's Summary

Rybrevant is indicated for the treatment of adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) exon 20 insertion mutations, as detected by an FDA-approved test, whose disease has progressed on or after platinum-based chemotherapy. Rybrevant is supplied as a single-dose 350 mg/7 mL (50 mg/mL) vial. Each vial is individually packed in a single carton. The recommended dosage of Rybrevant is based on baseline body weight and administered as an intravenous infusion after dilution. Dosing for patients with a body weight less than 80 kg, is 1050 mg, or three vials. For patients with a body weight greater than or equal to 80 kg, dosing is 1400 mg or four vials. Rybrevant is administered weekly for 4 weeks, with the initial dose as a split infusion in Week 1 on Day 1 and Day 2, then administered every 2 weeks thereafter.

Final Decision

Establish new HCPCS Level II code J9061 “Injection, amivantamab-vmjw, 2 mg”

Effective: 1/1/2022

Under long-standing policy, CMS will assign the dose descriptor in the smallest amount that could be billed in multiple units to accommodate a variety of doses, thus making coding more robust, and facilitating accurate payment and reporting of the exact dose administered.

CMS determined that 2 mg would be the smallest amount that could be billed in multiple units to accommodate a variety of doses and support streamlined billing, as only 999 units can appear on a claim line for Medicare fee-for-service.

HCPCS code C9083 “Injection, amivantamab-vmjw, 10 mg” will be discontinued on 12/31/2021 because it will be replaced with HCPCS code J9061.

RYLAZE- HCP210804RB2J4

Topic/Issue

Request to establish a new HCPCS Level II code to identify Rylaze.

Applicant's suggested language: Injection, asparaginase - Recombinant (Rylaze), per 1 mg.

Applicant's Summary

Rylaze is indicated as a component of a multi-agent chemotherapeutic regimen for the treatment of acute lymphoblastic leukemia (ALL) and lymphoblastic lymphoma (LBL) in adult and pediatric patients 1 month or older who have developed hypersensitivity to E. coli-derived asparaginase. Rylaze is supplied as a sterile, clear to opalescent, colorless to slightly yellow, preservative-free, ready-to-use solution for intramuscular injection, 10 mg/0.5 mL solution in a single-dose vial. Each carton of Rylaze contains 3 single-dose vials. The recommended dosage of Rylaze is 25 mg/m² administered intramuscularly every 48 hours. For an average adult patient weighing 70 kg measuring 160 cm (a body surface area of 1.7479 m² as calculated by <https://www.bcbst.com/providers/calculator.asp>), the dosage would be calculated at 43.69 mg (25 * 1.7479).

Final Decision

Establish new HCPCS Level II code J9021 "Injection, asparaginase, recombinant, (rylaze), 0.1 mg"

Effective: 1/1/2022

Under long-standing policy, CMS will assign the dose descriptor in the smallest amount that could be billed in multiple units to accommodate a variety of doses, thus making coding more robust, and facilitating accurate payment and reporting of the exact dose administered.

PYLARIFY- HCP2108044EA0X

Topic/Issue

Request to establish a new HCPCS Level II code to identify Pylarify.

Applicant's suggested language: A95XX, piflufolastat F 18 injection, diagnostic, per study dose.

Applicant's Summary

Pylarify (also known as piflufolastat F 18 injection) is a fluorine 18-based prostate-specific membrane antigen (PSMA)-targeted positron emission tomography (PET) imaging agent that acts as a radioactive drug. Piflufolastat F 18 injection is a radioactive diagnostic agent indicated for PET of PSMA positive lesions in men with prostate cancer: 1) with suspected metastasis who are candidates for initial definitive therapy; 2) with suspected recurrence based on elevated serum prostate-specific antigen (PSA) level. The purpose of the test is to scan for the presence and location of positive lesions, all eligible patients would have an established diagnosis of prostate cancer. No healthy patient would ever receive a piflufolastat F 18 injection. The piflufolastat F 18 injection will only be used after patients have been diagnosed for use with a radioactive diagnostic agent requiring a prescription.

Final Decision

Establish new HCPCS Level II code A9595 "Piflufolastat f-18, diagnostic, 1 millicurie"

Effective: 1/1/2022

Many newer drug or radiopharmaceutical products, such as those used to diagnose or treat cancer, require weight-based dosing. Thus, when dosage adjustments for individuals are made in small increments, codes have dose descriptors reflecting quantities that are less than the smallest available package size. We use smaller quantities in the code descriptors to facilitate more accurate billing. Improvement in billing accuracy by the use of smaller quantities in descriptors also facilitates the accurate tracking of payment for discarded drugs.

JEMPERLI- HCP210811G02XX

Topic/Issue

Request to establish a new HCPCS Level II code to identify JEMPERLI (dostarlimab-gxly).

Applicant's suggested language: JXXXX – Injection, dostarlimab-gxly (JEMPERLI), 1 mg

Applicant's Summary

JEMPERLI (dostarlimab-gxly) is a programmed death receptor-1 (PD-1)–blocking antibody indicated for the treatment of adult patients with mismatch repair deficient (dMMR) recurrent or advanced endometrial cancer, as determined by an FDA-approved test, that has progressed on or following prior treatment with a platinum-containing regimen. This indication is approved under accelerated approval based on tumor response rate and durability of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s). As JEMPERLI was evaluated and approved by the FDA under a unique Biologics License Application (BLA), it is a novel therapy. Therefore, no existing HCPCS code describes JEMPERLI. JEMPERLI is supplied in two single-dose vial (10 mL-200/6 or 20 mL-400/12) sizes. Each single-dose glass vial is filled with a solution of 29.25 mg/mL bupivacaine and 0.88 mg/mL meloxicam. The recommended dose of ZYNRELEF is based on the size of the surgical site up to a maximum dose of 400 mg/12 mg (14 mL).

Final Decision

1. Establish new HCPCS Level II code J9272 “Injection, dostarlimab-gxly, 10 mg”

Effective: 1/1/2022

2. HCPCS code C9082, effective 10/1/2021, will be discontinued on 12/31/2021 because it will be replaced with HCPCS code J9272.

CMS determined that 10 mg would be the smallest amount that could be billed in multiple units to accommodate a variety of doses and support streamlined billing, as only 999 units can appear on a claim line for Medicare fee-for-service.

CAMCEVI- HCP210811G3WUE

Topic/Issue

Request to establish a new HCPCS Level II code to identify CAMCEVI.

Applicant's suggested language: JXXXX – JXXXX, “leuprolide injectable emulsion, CAMCEVI 42mg”

Applicant’s Summary

CAMCEVI is indicated for the treatment of adult patients with advanced prostate cancer. CAMCEVI is a gonadotropin releasing hormone (GnRH) agonist which acts as an inhibitor of gonadotropin secretion. CAMCEVI must be administered by a healthcare provider and is supplied as a kit containing one sterile, pre-filled syringe for subcutaneous injection.

Final Decision

Establish new HCPCS Level II code J1952 “Leuprolide injectable, camcevi, 1 mg”

Effective: 1/1/2022

Under long-standing policy, CMS will assign the dose descriptor in the smallest amount that could be billed in multiple units to accommodate a variety of doses, thus making coding more robust, and facilitating accurate payment and reporting of the exact dose administered.

ADUHELM- HCP210804617F0

Topic/Issue

Request to establish a new HCPCS Level II code to identify Aduhelm.

Applicant's suggested language: J9XXX, Injection, aducanumab-avwa, 10 mg.

Applicant's Summary

ADUHELM is an amyloid beta (A β)-directed antibody indicated for the treatment of Alzheimer's disease. The accumulation of A β plaques in the brain is a defining pathophysiological feature of Alzheimer's disease. ADUHELM reduces A β plaques in the brain. ADUHELM is a unique biological, and as such, a unique HCPCS code is needed for reimbursement as a "single source drug or biological" under Section 1847A of the Social Security Act. ADUHELM is an A β -directed antibody indicated for the treatment of Alzheimer's disease. This indication is approved under accelerated approval based on reduction in A β plaques observed in patients treated with ADUHELM. Continued approval for this indication may be contingent upon verification of clinical benefit in confirmatory trial(s). ADUHELM is a recombinant human immunoglobulin gamma 1 (IgG1) monoclonal antibody directed against aggregated soluble and insoluble forms of A β . Titration is required for treatment initiation. The recommended maintenance dosage is 10 mg/kg. ADUHELM is an IV infusion administered over approximately one hour every four weeks. ADUHELM is a preservative-free, clear to opalescent, and colorless to yellow solution available in 170mg/1.7 mL (100 mg/mL) and 300 mg/3 mL (100 mg/mL) single-dose vials. Dilution is required.

Final Decision

Establish new HCPCS Level II code J0172 "Injection, aducanumab-avwa, 2 mg"

Effective: 1/1/2022

Under long-standing policy, CMS will assign the dose descriptor in the smallest amount that could be billed in multiple units to accommodate a variety of doses, thus making coding more robust, and facilitating accurate payment and reporting of the exact dose administered.

It is important to note that the HCPCS Level II code set is a coding system used to identify categories of items and services. It is not a methodology or system for making coverage or payment determinations for individual items or services. The existence or absence of a HCPCS Level II code does not mean that an item or service is covered or non-covered. For more information on the procedures CMS uses to process HCPCS code applications and make coding decisions, please click on the following link:

<https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/Downloads/2018-11-30-HCPCS-Level2-Coding-Procedure.pdf>

ABECMA- HCP2108028MAPV

Topic/Issue

Request to establish a new HCPCS Level II code to identify ABECMA.

Applicant's suggested language: JXXXX– Idecabtagene vicleucel, up to 460 million autologous B-cell maturation antigen (BCMA) directed CAR-positive T cells, including dose preparation procedures, per therapeutic dose.

Applicant's Summary

ABECMA is a B-cell maturation antigen (BCMA)-directed genetically modified autologous T cell immunotherapy. ABECMA targets BCMA, which is expressed on the surface of normal and malignant plasma cells. Antigen-specific activation of ABECMA results in chimeric antigen receptor (CAR) positive T cell proliferation, cytokine secretion, and subsequent cytolytic killing of BCMA-expressing cells. ABECMA is indicated for the treatment of adult patients with relapsed or refractory multiple myeloma after four or more prior lines of therapy, including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 monoclonal antibody. ABECMA is a CAR-positive T cell therapy targeting BCMA. The CAR construct includes an anti-BCMA scFv-targeting domain for antigen specificity, a transmembrane domain, a CD3-zeta T cell activation domain, and a 4-1BB costimulatory domain. A single dose of ABECMA contains a cell suspension of 300 to 460 x 10⁶ CAR-positive T cells. ABECMA is for autologous use and administered via intravenous infusion. ABECMA is supplied in one or more infusion bag(s) containing a frozen suspension of genetically modified autologous T cells in 5% dimethyl sulfoxide (DMSO). Each infusion bag of ABECMA is individually packaged in a metal cassette.

Final Decision

Establish new HCPCS Level II code Q2055 “Idecabtagene vicleucel, up to 460 million autologous b-cell maturation antigen (bcma) directed car-positive t cells, including leukapheresis and dose preparation procedures, per therapeutic dose”

Effective: 1/1/2022

ZYNRELEF- HCP210806B5NV4

Topic/Issue

Request to establish a new HCPCS Level II code to identify ZYNRELEF (bupivacaine and meloxicam) extended-release solution.

Applicant's suggested language: JXXXX: Bupivacaine and meloxicam, 1 mg

Applicant's Summary

ZYNRELEF is a unique, single source drug product. ZYNRELEF treats postsurgical pain and will be used in various sites of care including physician offices, ambulatory surgical centers (ASC) and hospital outpatient departments. There are currently no HCPCS codes that describe ZYNRELEF. ZYNRELEF is indicated in adults for soft tissue or periarticular instillation to produce postsurgical analgesia for up to 72 hours after bunionectomy, open inguinal herniorrhaphy, and total knee arthroplasty.

Final Decision

CMS does not believe that this product needs a unique HCPCS Level II code as it would not be paid separately, and is expected to be bundled and billed by providers with the procedure itself. Should Medicare have a need for a code to facilitate payment for Hospital Outpatient pass-through purposes, a code would be issued alongside that determination.

CELERA- HCP210811VGLHF

Topic/Issue

Request to establish a new HCPCS Level II code to identify Celera placental-derived allograft.

Applicant's Summary

Celera Placental-derived allograft products are minimally manipulated human amniotic and/or chorionic membrane derived from placental tissues. It is used for patients with chronic full thickness ulcers, 2nd and 3rd degree burns and patients undergoing various soft-tissue regenerative and reconstructive procedures requiring a biological barrier. It is used to support healing, repair or regeneration of soft tissue damaged due to disease or injury.

Final Decision

After review of the Food and Drug Administration's (FDA's) guidance, it does not appear to CMS that Celera placental-derived allograft is suitable for registration as a Human Cells, Tissues, and Cellular and Tissue-Based Product (HCT/P). CMS refers the applicant to the FDA's Tissue Reference Group (TRG) to obtain written feedback regarding how the product is appropriately regulated. After obtaining the FDA's written feedback, the applicant is welcome to submit a complete HCPCS code application in a subsequent coding cycle. Information for submitting questions to the TRG is located at: <https://www.fda.gov/vaccines-blood-biologics/tissue-tissue-products/tissue-reference-group>.

REVOSHIELD+- HCP210805W8TYH

Topic/Issue

Request to establish a new HCPCS Level II code to identify RevoShield+.

Applicant's suggested language: QXXXX – RevoShield+, per sq cm.

Applicant's Summary

The RevoShield+ is a minimally manipulated dual layer tissue-based product derived from the amniotic membrane of the human placenta. The intended use of the RevoShield + is to serve as a barrier to provide protective coverage from the surrounding environment for acute and chronic wounds such as pressure ulcers, diabetic foot ulcers and venous leg ulcers. Amniotic membrane grafts contain cytokines and growth factors which have been demonstrated to enhance chronic wound healing. It is available in various sizes: from 2x2cm up to 10x15cm.

Final Decision

RevoGen Biologics, submitted an application for RevoShield+, a dual layer tissue-based product derived from the amniotic membrane of the human placenta, which is stated by the applicant to be identical to Surgenex, LLC's SurGraft XT. A letter from the Food and Drug Administration's (FDA's) Tissue Reference Group (TRG) for SurGraft XT was provided as part of the application for RevoShield+. However, the FDA Establishment Identifier (FEI) number and FDA registration for RevoGen Biologic's RevoShield+ are different from the FEI and FDA registration for Surgenex, LLC's SurGraft XT. CMS would like to be sure that RevoShield+ and SurGraft XT are the same product, and are registered properly with the FDA. As a result, CMS refers the applicant to the FDA to ensure that the registration for RevoShield+ is in order, and to confer with the TRG to make sure the product they reviewed is the same product that is the subject of the HCPCS Level II application request. After obtaining the FDA's feedback pertaining to RevoShield+, the applicant is welcome to submit a complete HCPCS code application in a subsequent coding cycle.

TAG- HCP2108043LLVA

Topic/Issue

Request to establish a new HCPCS Level II code to identify TAG, a Triple Layer Amniotic Graft.

Applicant's suggested language: Q4XXX-TAG, per sq cm.

Applicant's Summary

TAG is a sterile, dehydrated, triple layer amniotic allograft composed solely from the amniotic membrane of donated human placental tissue. This triple layer amniotic allograft was reviewed and confirmed by the Food and Drug Administration's (FDA's) Tissue Reference Group (TRG), as meeting the criteria for regulation under 361 of the Public Health Service (PHS) Act as Human Cells, Tissues and Cellular and Tissue-Based Products (HCT/P) described in 21 CFR 1271.10. Following standard wound preparation, TAG is applied directly to the wound, providing coverage as a protective barrier for acute and chronic wounds. Sales/Marketing: TAG is currently marketed and available for use and purchase in the United States. TAG was first made available for market in the U.S., on February 13, 2021.

Final Decision

CMS notes that this application for the Q3 2021 cycle is identical to the application submitted for TAG in the Q2 2021 cycle, containing no new information. Flower Orthopedics, Corp., submitted an application for TAG, a triple layer amniotic graft, which is stated by the applicant to be identical to Surgenex, LLC's SurGraft® TL. A letter from the Food and Drug Administration's (FDA's) Tissue Reference Group (TRG) for SurGraft® TL was provided as part of the application for TAG. However, the FDA Establishment Identifier (FEI) number and FDA registration for Flower Orthopedics, Corp.'s TAG are different from the FEI and FDA registration for Surgenex, LLC's SurGraft® TL. CMS would like to be sure that TAG and SurGraft® TL are the same product, and are registered properly with the FDA. As a result, CMS again refers the applicant to the FDA to ensure that the registration for TAG is in order, and to confer with the TRG to make sure the product they reviewed is the same product that is the subject of the HCPCS Level II application request. After obtaining the FDA's feedback pertaining to TAG, the applicant is welcome to submit a complete HCPCS code application in a subsequent coding cycle.

ESANOFYL- HCP210804NEPL2

Topic/Issue

Request to modify HCPCS Level II code, Q4171 "Interfyl, 1 mg" to include Esanofyl.

Applicant's suggested language: Q4171 Interfyl, 1 mg and Esanofyl, 1 mg.

Applicant's Summary

Evolution Biologyx, LLC. requests to add Esanofyl to existing HCPCS Level II code Q4171, Interfyl, 1mg. Esanofyl is the same product as Interfyl with a private label contracted with the manufacturer. Esanofyl is a decellularized human placental connective-tissue matrix (CTM) derived from the placental disc (or "chorionic plate") of donated, normal, healthy, human, full-term placentas. It is composed of natural structural and biochemical extracellular matrix (ECM) components, including collagen, elastin, fibronectin, laminins, and glycosaminoglycans (GAGs). It is manufactured through minimal manipulation of the donated placental disc. When applied to a wound, the ECM's structure and biochemical contents (fibronectin, laminins, and GAGs) naturally attract cells, organize migration into the ECM, moisturize tissue to facilitate cell movement and nutrient supply, and provide points of adhesion for the patient's own cells. Esanofyl's CTM serves as a scaffold for recipient cells in the wound to regenerate soft tissue. Because it is not cross-linked and does not contain cells (trophoblasts that are potentially immune-reactive are removed from the ECM during processing), Esanofyl reduces the likelihood of immunogenic and inflammatory responses as compared to other Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps), thereby minimizing inflammation and scarring. Esanofyl is intended for use as the replacement or supplementation of damaged or inadequate integumental tissue by providing support for the body's normal healing processes. Indications for Esanofyl include treatment of deep dermal wounds, irregularly shaped and tunneling wounds, augmentation of deficient/inadequate soft tissue, and the repair of small surgical defects. Esanofyl is supplied in single-dose units: flowable product syringes containing 40mg, 45mg, 75mg, 170mg, and 275mg and particulate product in vials containing 50mg and 100mg.

Final Decision

The applicant submitted a letter dated October 15, 2004 from the Food and Drug Administration's (FDA's) Office of Combination Products (OCP), which does not reference Esanofyl and/or Interfyl. CMS notes that this letter is outdated, and it does not contain information specific to Esanofyl; as a result, we refer the applicant to the FDA's Tissue Reference Group (TRG) to obtain written feedback regarding how the product is appropriately regulated. After obtaining the FDA's written feedback, the applicant is welcome to submit a complete HCPCS code application in a subsequent coding cycle. Information for submitting questions to the TRG is located at: <https://www.fda.gov/vaccines-blood-biologics/tissue-tissue-products/tissue-reference-group>. The applicant also needs to submit an FDA Establishment Identifier (FEI) number for Esanofyl, and an FDA registration for their corporate entity (Evolution Biologyx, LLC.).

EXEM FOAM- HCP210813CU4RH

Topic/Issue

Request to establish a new HCPCS Level II code to identify ExEm Foam.

Applicant's Summary

ExEm Foam is a drug product indicated for use as a contrast agent for Sonohysterosalpingography, a transvaginal ultrasound imaging procedure that can be used to assess fallopian tube patency (openness). Assessment of fallopian tube patency is a fundamental test in a fertility work-up; occluded (non-patent) tubes could prevent sperm from reaching the ova. ExEm Foam is the first FDA-approved drug product that is indicated for use as a contrast agent with Sonohysterosalpingography, a transvaginal ultrasound imaging procedure, to assess fallopian tube patency in women with known or suspected infertility. Transvaginal ultrasound imaging with ExEm Foam is performed in outpatient hospital, physician's office, infertility clinic, and imaging center settings. ExEm Foam currently is the only FDA-approved drug product that allows for assessment of fallopian tube patency in the physician's office.

Preliminary Decision

This request is being deferred to a subsequent coding cycle because the scope of the request necessitates that additional consideration be given before CMS reaches a final decision.