Req#	Request	Published Preliminary Decision	Final Decision
	1. This document contains excerpts from CMS' HCPCS Application Summaries document for external code applications submitted in the 2019-2020 HCPCS coding cycle. For detailed information and full text, refer to the Application Summary documents as published on the CMS' HCPCS website. 2. Applications that were not timely completed and therefore not processed have been excluded from this list.		
19.001	Request to revise existing Level II HCPCS code Q2040, which currently reads: "Tisagenlecleucel, up to 250 million CAR-positive viable T cells, including leukapheresis and dose preparation procedures, per infusion", to instead read: "Tisagenlecleucel, up to 200,000 to 600 million CAR-positive viable T cells, including leukapheresis and dose preparation procedures, per infusion."	CMS discontinued existing code Q2040 "Tisagenlecleucel, up to 250 million car-positive viable T cells, including leukapheresis and dose preparation procedures, per infusion", Effectiveective 1/1/2019; and established new code Q2042 "Tisagenlecleucel, up to 600 million car-positive viable T cells, including leukapheresis and dose preparation procedures, per therapeutic dose", Effectiveective 1/1/2019. Newly established code Q2042 adequately describes Kymriah and accommodates FDA- approved dose ranges; and is available for assignment by insurers.	CMS discontinued existing code Q2040 "Tisagenlecleucel, up to 250 million car-positive viable T cells, including leukapheresis and dose preparation procedures, per infusion", Effective 1/1/2019; and established new code Q2042 "Tisagenlecleucel, up to 600 million car-positive viable T cells, including leukapheresis and dose preparation procedures, per therapeutic dose", Effective 1/1/2019. Newly established code Q2042 adequately describes Kymriah and accommodates FDA- approved dose ranges; and is available for assignment by insurers.
19.002	Request to establish a new Level II HCPCS code to identify epoetin alfa-epbx, Trade Name: Retacrit; for ESRD use. Applicant's suggested language: "Injection, Epoetin Alfa-epbx, Biosimilar, (Retacrit), 100 Units (for ESRD use)".	Established new Level II HCPCS code Q5105 "Injection, Epoetin Alfa, Biosimilar, (Retacrit) (For ESRD on dialysis), 100 units", Effective 7/1/2018.	CMS established Level II HCPCS code Q5105 "Injection, Epoetin Alfa, Biosimilar, (Retacrit) (For ESRD on dialysis), 100 units" Effectivee 7/1/2019; and then revised the newly established code to add the 4-character extension and instead read: "Injection, Epoetin Alfa-epbx, Biosimilar, (Retacrit) (For ESRD on dialysis), 100 units." Effective 01/01/2020
19.003	Request to establish a new Level II HCPCS code to identify epoetin alfa-epbx, Trade name: Retacrit; for non-ESRD use. Applicant suggested language: "Injection, Epoetin alfa-epbx, Biosimilar, (Retacrit), 1000 units (for non-ESRD use)."	Establish new Level II HCPCS code Q5106 "Injection, Epoetin Alfa, (Biosimilar), (Retacrit) (for non-ESRD use), 1000 Units", Effective 7/1/2018.	CMS established new Level II HCPCS code Q5106 "Injection, Epoetin Alfa, Biosimilar, (Retacrit) (for non-ESRD use), 1000 Units" Effective 7/1/2019; and then revised the newly established code to add the 4-character extension, and instead read: "Injection, Epoetin Alfa-epbx, Biosimilar, (Retacrit) (for non-ESRD use), 1000 Units." Effective 01/01/2020.
19.004	Request to establish a single new Level II HCPCS code to identify a 100% native, freeze-dried, Type-I bovine Collagen matrix for use for wound management, Trade names: ACM Surgical Collagen and ACM Surgical Extra Advanced Collagen. Applicant's suggested language: QXXXX "ACM Surgical Collagen/ACM Surgical Extra Advanced Collagen, per square centimeter".	Existing codes A6021 "Collagen dressing, sterile, size 16 square inch or less, each", A6022 "Collagen dressing, sterile, size more than 16 sq inch but less than or equal to 4 sq. in., each", or A6023 "Collagen dressing, sterile, size more than 48 sq in., each", depending on size, adequately describes ACM Surgical collagen and ACM Surgical extra advanced collagen. These codes are available for assignment by insurers if they deem appropriate.	Existing codes A6021 "Collagen dressing, sterile, size 16 square inch or less, each", A6022 "Collagen dressing, sterile, size more than 16 sq inch but less than or equal to 4 sq. in., each", or A6023 "Collagen dressing, sterile, size more than 48 sq in., each", depending on size, adequately describes ACM Surgical collagen and ACM Surgical extra advanced collagen. These codes are available for assignment by insurers if they deem appropriate.
19.005	Request to establish a new Level II HCPCS code to identify Pegfilgrastim-jmdb, Trade Name: fulphila. Applicant's suggested language: "Injection, pegfilgrastim-jmdb, biosimilar, (filphilia), 6 mg".	CMS established new Level II HCPCS code Q5108 "Injection, Pegfilgrastim-jmdb, Biosimilar, (fulphila), 0.5 mg." New code Q5108 adequately describes the product that is the subject of this request and is available for assignment by insurers.	CMS established new Level II HCPCS code Q5108 "Injection, Pegfilgrastim-jmdb, Biosimilar, (fulphila), 0.5 mg." New code Q5108 adequately describes the product that is the subject of this request and is available for assignment by insurers. Effective 07/12/2018
19.006	Request to establish a new Level II HCPCS code to identify pegfilgratim-cbqv, biosimilar, Trade Name: Udenyca. Applicant's suggested language: " Injection, pegfilgrastim-cbqv, biosimilar, (Udenyca), 0.5 mg."	CMS established new Level II HCPCS code Q5111 "Injection, Pegfilgrastim-cbqv, Biosimilar, (Udenyca), 0.5 mg", Effective 1/1/2019. New code Q5111 adequately describes the product that is the subject of this application, and is available for assignment by insurers.	CMS established Level II HCPCS code Q5111 "Injection, Pegfilgrastim-cbqv, Biosimilar, (Udenyca), 0.5 mg", Effective 1/1/2019. Existing code Q5111 adequately describes the product that is the subject of this application, and is available for assignment by insurers.
19.007	Request to establish a new Level II HCPCS code to identify filgrastim-aafi biosimilar, Trade Name: Nivestym. Applicant's suggested language: "Injection, filgrastim-aafi (G-CSF), biosimilar, (Nivestym), 1 microgram."	CMS established new Level II HCPCS code Q5110 "Injection, Filgrastim-aafi, Biosimilar, (Nyvestym), 1 microgram."	CMS established Level II HCPCS code Q5110 "Injection, Filgrastim-aafi, Biosimilar, (Nyvestym), 1 microgram". Effective 10/1/2018.
19.008	Request to establish eleven new Level II HCPCS codes to identify alternative payment models for radiation therapy. Applicants suggested language: SXXX1 Episode of care for radiation therapy to the head and neck SXXX2 Episode of care for radiation therapy to the esophagus SXXX3 Episode of care for radiation therapy to the thorax SXXX4 Episode of care for radiation therapy to the mediastinum SXXX5 Episode of care for radiation therapy to the breast SXXX6 Episode of care for radiation therapy to the chest wall SXXX7 Episode of care for radiation therapy to the abdomen SXXX8 Episode of care for radiation therapy to the pelvis SXXX9 Episode of care for radiation therapy to the prostate SXXX10 Episode of care for radiation therapy to the rectum SXXX11 Episode of care for radiation therapy to the metastasis	CMS refers the applicant to the American Medical Association for CPT coding guidance for the patient care service bundles described in this application. These services are not suitable for coding in HCPCS Level II.	CMS refers the applicant to the American Medical Association for CPT coding guidance for the patient care service bundles described in this application. These services are not suitable for coding in HCPCS Level II.
19.009	Request to revise existing Level II HCPCS code Q4163 which currently reads "Woundex, bioskin, per square centimeter" to include AxoBioMembrane. Applicant's suggested language: Q4163 "Amnion bio, WoundEX, AxoBioMembrane, per square centimeter"	Establish Q42XX "Amnion Bio or Axobiomembrane, per square centimeter". New code adequately describes the product that is the subject of this application.	Establish Q4211 "Amnion Bio or Axobiomembrane, per square centimeter". New code adequately describes the product that is the subject of this application.
19.011	Request to establish another Level II HCPCS code to identify gemcitabine in sodium chloride injection, Trade Name: Infugem.	Existing code J9201 "Injection, gemcitabine hydrochloride, 200 mg" adequately describes Infugem and is avaialble for assignment by insurers. The NDA approval, by itself, does not establish Infugem as a sole source product. There are multiple gemcitabine 10 mg/ml products provided in	1. Revise existing Level II HCPCS code J9201 to add "not otherwise specified"; to read: "Injection, gemcitabine hydrochloride, not otherwise specified, 200 mg" AND

	Applicant's suggested language: " J9XXX Gemcitabine in soduim chloride, ready-to-administer IV, 100 mg."	single-use bags that are AP rated in the FDA orange book. And in that case, Infugem can be included in the same code; and is not subject to the seperate pricing requirements under Medicare Part B ASP pricing program, as specified in section 1847A of the Social security Act. In addition, the notion of a significant therapeutic distinction is contradicted by the multiple AP ratings in the orange book.	2. Establish a new Level II HCPCS code J9199 "Injection, gemcitabine hydrochloride (Infugem), 200 mg" Effective: 1/1/2020
19.012	Request to establish a new Level II HCPCS code to identify trastuzumab-dttb, Trade Name: Ontruzant. Applicant's suggested language: "QXXXX Injection, Trastuzumab-dttb, Biosimilar (Ontruzant), 10 mg."	1) Revise existing Level II HCPCS code J9355 which currently reads: "Injection, trastuzumab, 10 mg", to instead read : "Injection, Trastuzumab, Excludes Biosimilar, 10 mg", Effective 7/1/2019; 2) Establish new Level II HCPCS code Q5112 "Injection, Trastuzumab-dttb, Biosimilar, (Ontruzant), 10 mg", Effective 7/1/2019. New code Q5112 will adequately describe Ontruzant.	CMS established new Level II HCPCS code Q5112 "Injection, trastuzumab-dttb, biosimilar, (Ontruzant), 10 mg". Revised existing Level II HCPCS code J9355 which currently reads: "Injection, trastuzumab, 10 mg", to instead read : "Injection, Trastuzumab, Excludes Biosimilar, 10 mg", Effective 7/1/2019.
19.013	Request to establish a Level II HCPCS code to identify Revefenacin inhalation solution, Trade Name: Yupelri. Applicant's suggested language: "QXXXX Revefenacin inhalation solution, fda-approved final product, noncompounded, administered through DME, unit-dose vial, 175 mcg."	Establish new Level II HCPCS code J7677 "Revefenacin Inhalation Solution, FDA-approved final product, non-compounded, administered through DME, 1 microgram". Effective 7/1/2019.	CMS established new Level II HCPCS code J7677 "Revefenacin inhalation solution, fda-approved final product, non-compounded, administered through DME, 1 microgram". Effective 07/01/2019
19.016	Request to establish a new Level II HCPCS code to identify a single-use vaginal tissue retraction sheath for use with vaginal speculum. Trade name: Nella VuSleeve. Applicant's suggested language: AXXXX Vaginal speculum retraction sleeve, disposable, each, for the Nella VuSleeve, a vaginal speculum accessory.	CMS refers the applicant to the American Medical Association (AMA) for coding guidance for reporting a VuSleeve, if used during a pelvic exam procedure.	New code not established to specifically identify the Vu Sleeve as it would be an incidental supply that is considered to be included in current coding. For coding guidance contact insurers in whose jurisdiction claims would be filed.
19.018	Request to establish a new Level II HCPCS code to identify esketamine nasal spray. Trade Name: Spravato Applicants suggested language: JXXXX "Nasal spray, esketamine, 28mg."	CMS is delaying its preliminary code recommendation for Spravato pending further considerartion.	CMS refers to new procedure codes established by CMS' Hospital and Ambulatory Payment Group: G2082 "Office or other outpatient visit for the evaluation and management of an established patient that requires the supervision of a physician or other qualified health care professional and provision of up to 56 mg of esketamine nasal self-administration, includes 2 hours post-administration observation" and G2083 "Office or other outpatient visit for the evaluation and management of an established patient that requires the supervision of a physician or other qualified health care professional and provision of greater than 56 mg esketamine nasal self-administration, includes 2 hours post-administration observation". These codes include a visit and a drug.
19.019	Request to establish a new Level II HCPCS code to identify abiraterone acetate. Trade name: Zytiga. Applicants suggested language: "Zytiga, oral 250 mg."	There is no need to establish another code to identify Zytiga because the drug would be reported using the appropriate, existing NDC code.	CMS has not identified claims processing or policy need on the part of any insurer to establish another code to identify Zytiga because the drug would be reported using the appropriate, existing NDC code.
19.022	Teva Pharmaceuticals USA, Inc. submitted a request to establish a new HCPCS Level II code to identify fremanezumab-vfrm. Trade name: Ajovy. Applicant's suggested language "Injection, fremanezumab-vfrm for subcutaneous use, per 225 mg."	Establish new Level II HCPCS code JXXXX "Injection, fremanezumab-vfrm, 1 mg (code may be used for Medicare when drug administered under the direct supervision of a physician, not for use when drug is self-administered)."	CMS established new Level II HCPCS code J3031 "Injection, fremanezumab-vfrm, 1 mg (code may be used for Medicare when drug administered under the direct supervision of a physician, not for use when drug is self-administered)." Effective 10/01/2019
19.023	Request to establish a new Level II HCPCS code to identify risperidone extended-release injectable suspension. Trade name: Perseris. Applicant's suggested language: Injection, risperidone (PERSERIS), per 1 mg.	1. Establish new Level II HCPCS code JXXXX "Injection, risperidone, (perseris), 0.5 mg 2. Revise existing code J2794 which currently reads: "Injection, risperidone, long acting, 0.5 mg"; to instead read: "Injection, risperidone (risperdal consta), 0.5 mg".	1. CMS established new Level II HCPCS code J2798 "Injection, risperidone, (perseris), 0.5 mg". Effective 10/01/2019 2. CMS revised existing code J2794 which currently reads: "Injection, risperidone, long acting, 0.5 mg"; to instead read: "Injection, risperidone (risperdal consta), 0.5 mg". Effective 10/01/2019
19.024	Request to establish a new Level II HCPCS code to identify NUZYRA (omadacycline) for injection. Applicant's suggested language: JXXXX "Injection, omadacycline, 100 mg".	Establish new Level II HCPCS code JXXXX "Injection, omadacycline, 1 mg".	CMS established new Level II HCPCS code J0121 "Injection, omadacycline, 1 mg". Effective 10/01/2019
19.025	Request to establish a new Level II HCPCS code to identify SYNOJOYNT (1% sodium hyaluronate). Applicant's suggested language: "synojoynt inj., per dose Hyaluronan or derivative, synojoynt, for intra-articular injection, per dose."	Establish new Level II HCPCS code JXXXX "Hyaluronan or derivative, synojoynt, for intra-articular injection, 1 mg."	CMS established new Level II HCPCS code J7331 "Hyaluronan or derivative, synojoynt, for intra-articular injection, 1 mg." Effective 10/01/2019
19.026	Request to revise existing Level II HCPCS code J3380 which currently reads "Injection, vedolizumab, 1 mg" to instead read "for intravenous injection, vedolizumab, 1 mg".	This request to revise existing code J3380 "Injection, vedolizumab, 1 mg", is not approved, because the proposed revision to specify intravenous administration is unnecessary, and does not improve the code. Existing Level II HCPCS modifier JA "administered intravenously" is available to be appended to this code if warranted, to specify intravenous route of administration. As there is no currently licensed subcutaneous route of administration for this product, a distinction based on a different route of administration is not indicated. If a subcutaneous route of administration is	This request to revise existing code J3380 "Injection, vedolizumab, 1 mg", is not approved, because the proposed revision to specify intravenous administration is unnecessary, and does not improve the code. Existing Level II HCPCS modifier JA "administered intravenously" is available to be appended to this code if warranted, to specify intravenous route of administration. As there is no currently licensed subcutaneous route of administration for this product, a distinction based on a different route of administration is not indicated. If a subcutaneous route of administration is subsequently cleared, existing

	subsequently cleared, existing modifier JB "administered subcutaneously" is available to be appended to this code if warranted.	modifier JB "administered subcutaneously" is available to be appended to this code if warranted.
19.027 Request to establish two new codes to identify AZEDRA (iobenguane I 131) injection, for intravenous use, indicated for treatment of adult and pediatric patients 12 years and older with iobenguane scan positive, unresectable, locally advanced or metastatic pheochromocytoma or paraganglioma who require systemic anticancer therapy. Trade name: Azedra. Applicant's suggested language: AXXXX: "I 131 iobenguane, dosimetric dose per 1 millicurie."	Establish new Level II HCPCS code A9XXX "Iodine I-131, iobenguane, 1 millicurie."	Establish new Level II HCPCS code A9590 "Iodine I-131, iobenguane, 1 millicurie." Effective 1/1/2020.
19.028 Request to establish one new Level II HCPCS code to identify Yutiq, and to revise existing code J7313 (Iluven). Applicant's suggested language for a new code: JXXXX Injection, fluocinolone acetonide, intravitreal implant (Yutiq), 0.01 mg. Applicant's suggested language for revised code: J7313 Injection, fluocinolone acetonide, intravitreal implant (Iluven), 0.01 mg.	1) Establish new Level II HCPCS code JXXXX "Injection, fluocinolone acetonide, intravitreal implant (Yutiq), 0.01 mg" 2) Revise existing code J7311 which currently reads: "Fluocinolone acetonide, intravitreal implant"; to instead read: "Injection, Fluocinolone acetonide, intravitreal implant (retisert), 0.01 mg 3) Revise existing code J7313 which currently reads: "Injection, fluocinolone acetonide, intravitreal implant, 0.01 mg"; to instead read: "Injection, fluocinolone acetonide, intravitreal implant (Iluven), 0.01 mg"	1) CMS established new Level II HCPCS code J7314 "Injection, fluocinolone acetonide, intravitreal implant (Yutiq), 0.01 mg" Effective 10/01/2019 2) Revised existing code J7311 which currently reads: "Fluocinolone acetonide, intravitreal implant"; to instead read: "Injection, Fluocinolone acetonide, intravitreal implant (retisert), 0.01 mg". 3) Revised existing code J7313 which currently reads: "Injection, fluocinolone acetonide, intravitreal implant, 0.01 mg"; to instead read: "Injection, fluocinolone acetonide, intravitreal implant (iluven), 0.01 mg"
19.030 Request to establish a new Level II HCPCS code to identify Novafix, a dehydrated human amniotic membrane allograft indicated for use in the management of wounds. Trade name: Novafix™.	Establish Q42XX "Novafix, per square centimeter"	Establish new Level II HCPCS code Q4208 "Novafix, per square centimeter"
19.031 Request to establish a new Level II HCPCS code to identify SurGraft, a "sheet-like" human amniotic membrane scaffold which "functions as a wound covering". Trade name: SurGraft®.	Establish Q42XX "Surgraft, per square centimeter"	Establish new Level II HCPCS code Q4209 "Surgraft, per square centimeter". Effective 10/01/2019
19.032 Request to establish a new Level II HCPCS code to identify Prograf Granules (tacrolimus for oral suspension). Trade name: Prograf Granules. Applicant's suggested language: JXXXX tacrolimus, granules, per 0.2 mg.	Existing code J7507 "Tacrolimus, immediate release, oral, 1 mg", adequately describes Prograf Granules and is available for assignment by insurers. The NDA approval, by itself, does not establish Prograf Granules as a sole source product. There are multiple oral forms of Tacrolimus that are AP rated in the FDA orange book. And in that case, Prograf Granules can be included in the same code. Separate pricing in accordance with section 1847A of the Social Security Act does not apply to this multisource drug. CMS has consulted its ESRD staff and a specific code for ESRD use is not neccessary because, if used, the immunosuppressant would not be considered a renal dialysis service.	Existing code J7507 "Tacrolimus, immediate release, oral, 1 mg", adequately describes Prograf Granules and is available for assignment by insurers. The NDA approval, by itself, does not establish Prograf Granules as a sole source product. There are multiple oral forms of Tacrolimus that are AP rated in the FDA orange book. And in that case, Prograf Granules can be included in the same code. Separate pricing in accordance with section 1847A of the Social Security Act does not apply to this multisource drug. CMS has consulted its ESRD staff and a specific code for ESRD use is not neccessary because, if used, the immunosuppressant would not be considered a renal dialysis service.
19.033 Request to revise existing Level II HCPCS code Q4163 which currently reads "Woundex, bioskin, per square centimeter"; to include "Membrane Graft and Membrane Wrap" human amniotic allograft membranes. Trade names: Membrane Graft and Membrane Wrap. Applicant's suggested language: Q4163 "Amnion bio, WoundEX, Membrane Graft and Membrane Wrap, per square centimeter."	Establish Q42XX "Membrane Graft or Membrane Wrap, per square centimeter"	Establish new Level II HCPCS code Q4205 "Membrane Graft or Membrane Wrap, per square centimeter". Effective 10/01/2019
19.034 Request to establish a single new Level II HCPCS code to identify Human amniotic flowable allografts. Trade names: Fluid Flow and Fluid GF. Applicant's suggested language: QXXXX Fluid Flow and Fluid	Establish Q42XX "Fluid Flow or Fluid Gf, 1 cc"	Establish new Level II HCPCS code Q4206 "Fluid Flow or Fluid Gf, 1 cc". Effective 10/01/2019
19.036 Request to establish a new Level II HCPCS code to identify a human acellular dehydrated dermis regenerative tissue matrix. Trade name: BellaCell HD. Applicant's suggested language: "BellaCell HD Regenerative Tissue Matrix, per square centimeter."	Establish Q42XX "Bellacell HD or Surederm, per square centimeter"	Establish new Level II HCPCS code Q4220 "Bellacell HD or Surederm, per square centimeter". Effective 10/01/2019
19.037 Request to establish a new Level II HCPCS code to identify a human acellular dermal matrix. Trade name: SureDerm. Applicant's suggested language: "SureDerm Acellular Dermal Matrix, per square centimeter."	Establish Q42XX "Bellacell HD or Surederm, per square centimeter"	Establish new Level II HCPCS code Q4220 "Bellacell HD or Surederm, per square centimeter". Effective 10/01/2019
19.039 Request to establish a new Level II HCPCS codes to identify an injectable drug indicated for use in previously treated adults and adolescents (12 years of age and older) with hemophilia A (congenital Factor VIII deficiency) for: on-demand treatment and control of bleeding episodes, perioperative management of bleeding, and routine prophylaxis to reduce the frequency of bleeding episodes. Trade Name: Jivi. Applicants suggested language: JXXXX "antihemophilic factor (recombinant) PEGylated-aucl, Jivi, per IU."	Establish new Level II HCPCS code J7208 Injection, factor viii, (antihemophilic factor, recombinant), pegylated-aucl, (jivi), 1 i.u.". Effective 07/01/2019.	Establish new Level II HCPCS code J7208 "Injection, factor viii, (antihemophilic factor, recombinant), pegylated-aucl (jivi), 1 i.u.". Effective 07/01/2019.
19.040 Request to establish a new Level II HCPCS code to identify Takhzyro™ (lanadelumab-flyo), indicated for prophylaxis to prevent attacks of hereditary angioedema (HAE) in patients 12 years and older. Brand name: Takhzyro.	Establish new Level II HCPCS code JXXXX "Injection, lanadelumab-flyo, 1 mg (code may be used for Medicare when drug administered under the direct supervision of a physician, not for use when drug is self-administered)"	CMS established new Level II HCPCS code J0593 "Injection, lanadelumab-flyo, 1 mg (code may be used for Medicare when drug administered under the direct supervision of a physician, not for use when drug is self-administered)" Effective 10/01/2019

	Applicant's suggested language: Jxxxx- injection, lanadelumab-flyo, per 10 mg.	
19.041	Request to revise existing Level II HCPCS code Q4163 by adding Axolotl Graft and Axolotl DualGraft Applicant's suggested language: Q4163 WoundEX, BioSkin, Axolotl Graft, Axolotl DualGraft, per square centimeter	Establish Q42XX "Axolotl Graft or Axolotl Dualgraft, per square centimeter"	Establish Q4210 "Axolotl Graft or Axolotl Dualgraft, per square centimeter"
19.042	Request to establish a new Level II HCPCS code to identify sufentanil sublingual tablet, Trade Name: Dsuvia™. Applicant's suggested language: JXXXX "sufentanil (DSUVIA), sublingual (for healthcare provider administration), 30 mcg.	Dsuvia is not suitable for coding in Level II HCPCS outside of CMS' pass-through coding process due to setting of use. We refer the applicant to CMS' pass-through program for consideration of coding for reporting use in HOPPS and ASC settings.	Dsuvia is not suitable for coding in Level II HCPCS due to setting of use.
19.043	Request to establish a new Level II HCPCS code to identify Herzuma trastuzumab-pkrb, Trade Name: Herzuma. Applicant's suggested language: JXXXX "Injection, trastuzumab-pkrb, 10 mg."	1) Revise existing Level II HCPCS code J9355 which currently reads: "Injection, trastuzumab, 10 mg" to instead read: "Injection, trastuzumab, excludes biosimilar, 10 mg", Effective 7/1/2019 2) Establish new Level II HCPCS code Q5113 "Injection, trastuzumab-pkrb, biosimilar (Herzuma), 10 mg", Effective 7/1/2019. Newly established code Q5113 will adequeately describe Herzuma.	1) CMS revised existing Level II HCPCS code J9355 which currently reads: "Injection, trastuzumab, 10 mg" to instead read: "Injection, trastuzumab, excludes biosimilar, 10 mg", Effective 7/1/2019 2) CMS established new Level II HCPCS code Q5113 "Injection, trastuzumab-pkrb, biosimilar (Herzuma), 10 mg", Effective 7/1/2019.
19.044	Request to establish a new Level II HCPCS code to identify rituximab-abbs, an injectable drug. Trade Name: Truxima. Applicant's recommended language: JXXXX "Injection, rituximab-abbs, 10 mg."	Establish new Level II HCPCS code Q5115 "Injection, rituximab-abbs, biosimilar, (truxima), 10 mg". Effective 7/1/2019.	CMS established new Level II HCPCS code Q5115 "Injection, rituximab-abbs, biosimilar, (truxima), 10 mg". Effective 07/01/2019
19.046	Request to establish a new Level II HCPCS code to identify moxetumomab pasudotox-tdfk, Trade Name: Lumoxiti. Applicant's suggested language: JXXXX "Injection, moxetumomab pasudotox-tdfk, 0.01 mg."	Establish new Level II HCPCS code JXXXX "Injection, moxetumomab pasudotox-tdfk, 0.01 mg"	CMS established new Level II HCPCS code J9313 "Injection, moxetumomab pasudotox-tdfk, 0.01 mg." Effective 10/01/2019
19.047	Request to establish a single new Level II HCPCS code to identify human amniotic flowable allograft, intended for homologous use and to support the repair of soft tissue injury, Trade names: Axolotl Ambient and Axolotl Cryo. Applicant's suggested language: QXXXX Axolotl Ambient, Axolotl Cryo, per milliliter.	Establish Q42XX "Axolotl Ambient or Axolotl Cryo, 0.1 mg"	Establish new Level II HCPCS code Q4215 "Axolotl Ambient or Axolotl Cryo, 0.1 mg"
19.048	Request to establish a new Level II HCPCS code to identify iclaprim mesylate, Trade Name: Xultenba.	Xultenba is not suitable for coding in Level II HCPCS outside of CMS' pass-through coding process due to setting of use. We refer the applicant to CMS' pass-through program for consideration of coding for reporting use in HOPPS and ASC settings. For hospital inpatient use the product is included in the bundled payment.	Xultenba is not suitable for coding in Level II HCPCS outside of CMS' pass-through coding process due to setting of use. We refer the applicant to CMS' pass-through program for consideration of coding for reporting use in HOPPS and ASC settings. For hospital inpatient use the product is included in the bundled payment.
19.049	Request to establish a new Level II HCPCS code to identify a 3 mm cylindrical ophthalmic drug insert. Trade Name: Dextenza. Applicant's suggested language: JXXXX, Dextenza, Ophtalmic insert, lacrimal, dexamethasone, 0.4 mg.	Establish new Level II HCPCS code JXXXX "Dexamethasone, lacrimal ophthalmic insert, 0.1 mg"	CMS established new Level II HCPCS code J1096 "Dexamethasone, lacrimal ophthalmic insert, 0.1 mg" Effective 10/01/2019
19.051	Request to revise existing Level II HCPCS code Q4169 which identifies Artacent™ Wound to include single and dual layer products. Applicant's suggested revised language: Q4169 Artacent Wound, single or dual layer, per sq cm.	Existing code Q4169 "Artacent wound, per square centimeter", adequately describes the wound products as reflected in the FDA license.	Existing code Q4169 "Artacent wound, per square centimeter", adequately describes the wound products as reflected in the FDA license.
19.052	Request to establish a new Level II HCPCS code to identify a "healing patch" comprised of Artacent Cord Human Umbilical Cord, Trade Name: Artacent Cord.	Establish Q42XX "Artacent cord, per square centimeter"	Establish Level II HCPCS code Q4216 "Artacent cord, per square centimeter". Effective 10/01/2019
19.053	Request to establish a new Level II HCPCS code to identify Phenylephrine and Ketorolac ophthalmic solution. Trade Name: Omidria. Applicant's suggested language: JXXXX- Injection, phenylephrine and ketorolac 1%/0.3%, 4 ml vial.	Establish new Level II HCPCS code JXXXX "Phenylephrine 10.6 mg/ml and Ketorolac 2.88 mg/ml ophthalmic irrigation solution, 1 ml"	CMS established new Level II HCPCS code J1097 "Phenylephrine 10.16 mg/ml and Ketorolac 2.88 mg/ml ophthalmic irrigation solution, 1 ml" Effective 10/01/2019
19.054	Request to establish a new Level II HCPCS code to identify plazomicin. Trade Name: Zemdri. Applicant's suggested language: JXXXX- Injection, plazomicin, 5 mg.	Establish new Level II HCPCS code J02XX "Injection, Plazomicin, 5 mg".	CMS established new Level II HCPCS code J0291 "Injection, Plazomicin, 5 mg". Effective 01/01/2019
19.055	Request to establish a new Level II HCPCS code to identify Human Keratin Matrix derived from human hair. Trade Name: ProgenaMatrix™.	Establish Q42XX "Progenamatrix, per square centimeter"	Establish new Level II HCPCS code Q4222 "Progenamatrix, per square centimeter". Effective 10/01/2019

19.056	Request to establish a new Level II HCPCS code to identify patisiran. Trade Name: Onpattro (patisiran). Applicant's suggested language: JXXXX- Injection, patisiran, 0.1 mg.	Establish new Level II HCPCS code JXXXX "Injection, Patisiran, 0.1 mg"	CMS established new Level II HCPCS code J0222 "Injection, Patisiran, 0.1 mg" Effective 10/01/2019
19.057	Request to establish a new Level II HCPCS code to identify cemiplimab-rwlc, Trade Name: Libtayo cemeplimab-rwlc. Applicant's suggested language: J9XXX "Injection, cemiplimab-	Establish new Level II HCPCS code J9XXX "Injection, cemiplimab-rwlc, 1 mg."	CMS established new Level II HCPCS code J9119 "Injection, cemiplimab-rwlc, 1 mg." Effective 10/01/2019
19.058	Request to establish a new Level II HCPCS code to identify apatulamide, an oral drug. Trade Name: Erleada. Applicant's suggested language: JXXXX "Apalutamide, oral, 60 mg."	There is no need to establish another code to identify Erleada because the drug would be reported using the appropriate, existing NDC code.	CMS has not identified claims processing or policy need on the part of any insurer to establish another code to identify Erleada because the drug would be reported using the appropriate, existing NDC code.
19.059	Request to revise existing Level II HCPCS code Q4165 "Keramatrix, per square centimeter" to add an additional similar product, Kerasorb. Applicant's suggested language: Q4165 Keramatrix, per square centimeter or Kerasorb Wound Matrix, per square centimeter.	Revise existing code Q4165, which currently reads "Keramatrix, per square centimeter", to instead read "Keramatrix or Kerasorb, per square centimeter". Revised code Q4165 adequately describes Keramatrix and Kerasorb and will be available for assignment by insurers if they deem appropriate.	Revise existing code Q4165, which currently reads "Keramatrix, per square centimeter", to instead read "Keramatrix or Kerasorb, per square centimeter".
19.060	Request to establish a new Level II HCPCS code to identify Bendamustine hydrochloride, Trade Name: Belrapzo. Applicant's suggested language: J9XXX "Injection, bendamustine HCL (Belrapzo), per 1 mg."	Establish new Level II HCPCS code J9036 "Injection, bendamustine hydrochloride, (Belrapzo/Bendamustine), 1 mg", Effective 7/1/2019	CMS established new Level II HCPCS code J9036 "Injection, bendamustine hydrochloride, (Belrapzo/Bendamustine), 1 mg". Effective 07/01/2019
19.061	Request to establish a new Level II HCPCS code to identify a human amnion allograft, Trade Name: AlloGen Liquid. Applicants suggested language: QXXXX AlloGen injectable, per ml.	Establish Q42XX "Allogen, per cc"	Establish new Level II HCPCS code Q4212 "Allogen, per cc"
19.062	Request to establish a new Level II HCPCS code to identify Ravulizumab-cwvz, an injectable drug proposed for treatment of adult patients with paroxysmal nocturnal hemoglobinuria (PNH). Trade Name: Ultomiris™. Applicant's suggested language: JXXXX- injection, ravulizumab-	Establish new Level II HCPCS code JXXXX "Injection, ravulizumab-cwvz, 10 mg"	CMS established new Level II HCPCS code J1303 "Injection, ravulizumab-cwvz, 10 mg". Effective 10/01/2019
19.063	Request to establish a new Level II HCPCS code to identify a "dehydrated cell and protein concentrate (dCPC) injectable derived from human amniotic fluid", Trade Name: Ascent™. Applicant suggested language: Qxxxx - Ascent™, per milligram	Establish Q42XX "Ascent, 0.5 mg"	Establish new Level II HCPCS code Q4213 "Ascent, 0.5 mg"
19.064	Request to establish a new Level II HCPCS code to identify an injectable sodium hyaluronate. Trade Name: Triluron. Applicant's suggested language: JXXXX, Hyaluronan or derivative, Triluron, for intra-articular injection, 1 mg.	Establish new Level II HCPCS code J7XXX "Hyaluronan or derivative, Triluron, for intra-articular injection, 1 mg"	CMS established new Level II HCPCS code J7332 "Hyaluronan or derivative, Triluron, for intra-articular injection, 1 mg". Effective 10/01/2019
19.065	Request to establish a new Level II HCPCS codes to identify aripiprazole lauroxil. Trade Name: Aristada Initio. Applicants suggested language: JXXXX, injection, aripiprazole lauroxil single starting dose, 1 mg.	1) Establish new Level II HCPCS code JXXXX "Injection, aripiprazole lauroxil, (Aristada Initio), 1 mg" 2) Revise existing code J1942 which currently reads: "Injection, aripiprazole lauroxil, 1 mg"; to instead read: "Injection, aripiprazole lauroxil, (Aristada), 1 mg"	1) Establish new Level II HCPCS code J1943 "Injection, aripiprazole lauroxil, (Aristada Initio), 1 mg" Effective 10/1/19 2) Discontinue existing code J1942 which currently reads: "Injection, aripiprazole lauroxil, 1 mg Effective 10/1/19 3) Establish new level II HCPCS code J1944 "Injection, aripiprazole lauroxil, (Aristada), 1 mg" Effective 10/1/19
19.066	Request to establish a new Level II HCPCS code to identify tagraxofusp-erzs, an injctable drug, Trade Name: Elzonris. Applicant's suggested language: J9XXX "Elzonris™ (tagraxofusp-	Establish new Level II HCPCS code JXXXX "Injection, tagraxofusp-erzs, 10 micrograms"	Establish new Level II HCPCS code J9269 "Injection, tagraxofusp-erzs, 10 micrograms". Effective 10/01/2019
19.067	Request to create a coding distinction between parenteral nutrition solution lipid formulations currently included in code category B4185 in a way that would separately code a single, specific fish oil solution by brand name, "Omegaven"; and include all soybean oil- containing lipid solutions, (including those also containing lipids from fish and other sources), in code B4185. Applicant's suggested language: Establish new code: "Parenteral nutrition solution, per 5 grams fish oil triglycerides (Omegaven)" Revise existing code B4185 which currently reads "Parenteral nutrition solution, per 10 grams lipids", to instead read "Parenteral nutrition solution, per 10 grams soybean oil-containing lipids"	Existing code B4185 "Parenteral Nutrition Solution, per 10 grams lipids", adequately describes lipid parental nutrition solutions. As such this code may be used to identify Omegaven. The clinical evidence submitted with this application is insuficient to support the applicant's claim of significant therapeutic distinction.	1. Revise B4185 to read "Parenteral nutrition solution, not otherwise specified, 10 grams lipids". Effective. 01/01/2020 2. Establish new Level II HCPCS code B4187 "Omegaven, 10 grams lipids". Effective. 01/01/2020
19.068	Request to establish a new Level II HCPCS code to identify acellular dermal matrix, Trade Name: Artia.	Artia is not suitable for coding in Level II HCPCS as it is used exclusively in hospital inpatient and outpatient settigns. For inpatient use, Artia would be bundled in hospital payment. CMS re-refers applicant to CMS' pass-through coding program for consideration of pass-through coding for use HOPPS settings.	Artia is not suitable for coding in Level II HCPCS as it is used exclusively in hospital inpatient and outpatient settigns. For inpatient use, Artia would be bundled in hospital payment. CMS re-refers applicant to CMS' pass-through coding program for consideration of pass-through coding for use HOPPS settings.
19.069	Request to establish a new Level II HCPCS code to identify trastuzumab and hyaluronidase-oysk. Trade name: Herceptin Hylecta. Applicant's suggested language for J-code "Subcutaneous Injection, trastuzumab and hyaluronidase, 10 mg."	Establish new Level II HCPCS code J9356 "Injection, trastuzumab, 10 mg and hyaluronidase-oysk", Effective 7/1/2019.	CMS established new Level II HCPCS code J9356 "Injection, Trastuzumab, 10 mg and hyaluronidase-oysk". Effective 07/01/2019

	Request		
19.070	Request to establish a new Level II HCPCS code to identify an allograft adipose matrix, Trade Name: Renuva® Applicant's suggested language: Qxxxx "Renuva Allograft Adipose Matrix, 0.5cc".	The CMS spent a significant amount of time carefully considering this application and in the process, communicated with the applicant several times, in February, March and April of this year, and researching policy information and other supplemental materials provided by the applicant. Yet CMS was unable to find policy on the part of any insurance sector that would indicate a need for a code to identify a non-autologous adipose graft for the clinical indications specified by the applicant, in a physician's office setting.	The CMS spent a significant amount of time carefully considering this application and in the process, communicated with the applicant several times, in February, March and April of this year, and researching policy information and other supplemental materials provided by the applicant. CMS also accepted a single billing document provided by the applicant following the May 13th, 2019 HCPCS public meeting, as well as additional information provided to CMS during in-person meeting on 09/20/2019. Yet CMS was unable to find policy on the part of any insurance sector that would indicate a need for a code to identify a non-autologous adipose graft for the clinical indications specified by the applicant, in a physician's office setting.
19.071	Request to establish a new Level II HCPCS code to identify an umbilical cord allograft, Trade Name: Cellesta™ Cord. Applicant's suggested language: QXXXX "Cellesta™ Cord, per square centimeter."	Establish Q42XX "Cellesta cord, per square centimeter"	Establish new Level II HCPCS code Q4214 "Cellesta cord, per square centimeter"
19.072	Request to establish a new Level II HCPCS code to identify a dual layer human amniotic membrane allograft, Trade Name: Cellesta™ Duo. Applicant's suggested language: QXXXX "Cellesta™ Duo, per square centimeter."	Revise existing code Q4184 which currently reads "Cellesta, per square centimeter", to instead read "Cellesta or Cellesta Duo, per square centimeter". Revised code adequately describes Cellesta and Cellesta Duo and will be available for assignment by insurers if they deem appropriate.	Revise existing code Q4184 which currently reads "Cellesta, per square centimeter", to instead read "Cellesta or Cellesta Duo, per square centimeter". Revised code adequately describes Cellesta and Cellesta Duo and will be available for assignment by insurers if they deem appropriate.
19.073	Request to establish a new Level II HCPCS code to identify Cablivi (Caplacizumab-yhdp), Trade Name: Cablivi. Applicant's suggested language: J9XXX "Injection, caplacizumab-yhdp, 10 mg."	CMS has not identified a claims processing need to establish another code to report caplacizumab-yhdp. For Medicare the product is self-administered at home and therefore, not reportable. To report use in HOPPS refer to code C9047 Injection, caplacizumab-yhdp, 1 mg. Then NDC code may also be used to report to non-Medicare insurers.	CMS has not identified a claims processing need to establish another code to report caplacizumab-yhdp. For Medicare the product is self-administered at home and therefore, not reportable. To report use in HOPPS refer to code C9047 Injection, caplacizumab-yhdp, 1 mg. Then NDC code may also be used to report to non-Medicare insurers.
19.074	Request to establish a new Level II HCPCS code to identify an autologous, homologous human skin product. Trade Name: MyOwn Skin™ Applicant's suggested language: QXXXX "MyOwn Skin™, per square centimeter."	Establish Q42XX "Myown Skin, Includes Harvesting And Preparation Procedures, per square centimeter"	Establish new Level II HCPCS code Q4226 "MyOwn skin, includes harvesting and preparation procedures, per square centimeter".
19.075	Request to establish a new Level II HCPCS code to identify a corticosteroid-eluting implant indicated for the treatment of nasal polyps in patients 18 years of age who have had ethmoid sinus surgery. Trade Name: Sinuva (mometasone furoate) Sinus Implant. Applicant's suggested language: JXXXX, mometasone furoate, 1,350 mcg, sinus drug implant (Sinuva).	1) Establish new Level II HCPCS code J7XXX "Mometasone furoate, implant, 10 micrograms" 2) Discontinue existing code S1090, which currently reads: "Mometasone furoate sinus implant, 370 micrograms", because it is duplicative of JXXXX.	1) CMS established new Level II HCPCS code J7401 "Mometasone furoate sinus implant, 10 micrograms". Dose descriptor of 10 micrograms is consistent with CMS' longstanding convention of using the lowest common denominator. This code can be reported in multiples in the units column on the claim form. 2) Discontinued existing code S1090, which currently reads: "Mometasone furoate sinus implant, 370 micrograms", because it is duplicative of J7401, Effective 10/1/19.
19.076	Request to establish a new Level II HCPCS code to identify an injectable folate analog, Trade Name: Khapzory. Applicant's suggested language: JXXXX "Injection, levoleucovorin, 1 mg."	Revise existing Level II HCPCS code J0641 which currently reads: "Injection, levoleucovorin calcium, 0.5 mg"; to instead read: "Injection, levoleucovorin, 0.5 mg". Multisource J0641 as revised adequately describes Khapzory.	1. CMS revised existing Level II HCPCS code J0641 which currently reads: "Injection, levoleucovorin calcium, 0.5 mg"; to instead read: "Injection, levoleucovorin, not otherwise specified, 0.5 mg". Effective. 10/01/2019. 2. CMS established new Level II HCPCS code J0642 "Injection, levoleucovorin (khapzory), 0.5 mg". Effective. 10/01/2019.
19.078	Request to establish a new Level II HCPCS code to identify a human rabies immunoglobulin (HRIG) biological indicated for passive, transient post-exposure prophylaxis (PEP) of rabies infection, when given immediately after contact with a rabid or possibly rabid animal. Trade Name: Kedrab, Rabies Immune Globulin (Human). Applicant's suggested language: "JXXXX Injection, rabies immune globulin, human, solvent/detergent and heat-treated (Kedrab), 150 i.u."	The CMS has carefully considered this request to establish a unique Level II HCPCS code to identify Kedrab, together with input from the drug pricing component of CMS' Hospital and Ambulatory payment group and from the American Medical Association, in follow-up to specific concerns noted by Kedrion within this application. In its final coding decision to a prior (2018-2019) request from Kedrion to establish distinct Level II HCPCS codes for Rabies Immune globulin products, the CMS discussed that the taxonomy for Rabies Immune globulin products resides in the HCPCS Level I Current Procedural Terminology (CPT) code set, maintained by the American Medical Association (AMA). And we referred Kedrion to the AMA to resolve the CPT coding concerns expressed in its 2018-2019 application to CMS for a Level II HCPCS code. It is our understanding that Kedrion did not submit an application to the AMA for a unique code to identify Kedrab, and this specific request was only made to CMS. As the AMA maintains the series of Rabies immune globulin codes, CMS suggests that Kedrion provide the AMA with the opportunity to consider its request to uniquely code Kedrab within its series of Rabies immune globulin codes. In the meantime, CMS has a mechanism to establish a separate price for Kedrab in accordance with section 1847A of the Social Security Act.	The CMS has carefully considered this request to establish a unique Level II HCPCS code to identify Kedrab, together with input from the drug pricing component of CMS' Hospital and Ambulatory payment group and from the American Medical Association, in follow-up to specific concerns noted by Kedrion within this application. In its final coding decision to a prior (2018-2019) request from Kedrion to establish distinct Level II HCPCS codes for Rabies Immune globulin products, the CMS discussed that the taxonomy for Rabies Immune globulin products resides in the HCPCS Level I Current Procedural Terminology (CPT) code set, maintained by the American Medical Association (AMA). And we referred Kedrion to the AMA to resolve the CPT coding concerns expressed in its 2018-2019 application to CMS for a Level II HCPCS code. It is our understanding that Kedrion did not submit an application to the AMA for a unique code to identify Kedrab, and this specific request was only made to CMS. As the AMA maintains the series of Rabies immune globulin codes, CMS suggests that Kedrion provide the AMA with the opportunity to consider its request to uniquely code Kedrab within its series of Rabies immune globulin codes. In the meantime, CMS has a mechanism to establish a separate price for Kedrab in accordance with section 1847A of the Social Security Act.
19.079	Request to establish a new Level II HCPCS code to identify an anti-neoplastic agent and immunomodulatory in the form of a	Establish new Level II HCPCS code JXXXX "Injection, mogamulizumab-kpkc, 1 mg"	CMS established new Level II HCPCS code J9204 "Injection, mogamulizumab-kpkc, 1 mg." Effective 10/01/2019.

	recombinant humanized monoclonal antibody that targets CC chemokine receptor 4 (CCR4)-expressing cells, Trade Name: Poteligeo. Applicants suggested language: J9XXX "Injection,		
19.080	Request to establish a new Level II HCPCS code to identify coagulation factor Xa (recombinant), inactivated-zhzo. Trade Name: Andexxa. Applicant's suggested language: JXXXX, Injection, coagulation factor Xa (recombinant), inactivated-zhzo (Andexxa), 100 mg.	Andexxa is not suitable for coding in Level II HCPCS outside of CMS' pass-through coding process due to setting of use. Existing pass-through code C9041 "Injection, coagulation factor Xa (recombinant), inactivated (andexxa), 10 mg" is available for assignment by insurers, if they deem appropriate to identify hospital outpatient use.	Andexxa is not suitable for coding in Level II HCPCS outside of CMS' pass-through coding process due to setting of use. Existing pass-through code C9041 "Injection, coagulation factor Xa (recombinant), inactivated (andexxa), 10 mg" is available for assignment by insurers, if they deem appropriate to identify hospital outpatient use. For coding guidance contact the insurers in whose jurisdiction claims would be filed.
19.081	Request to revise existing Level II HCPCS code J1443, which currently reads: "Injection, ferric pyrophosphate citrate solution, 0.1 mg of iron", to instead read: "Ferric pyrophosphate citrate solution ampule, 0.1 mg of iron in hemodialysate".	This request to revise existing code J1443 is not approved, because the requested revision does not improve the code. The existing code J1443 "Injection, ferric pyrophosphate citrate solution, 0.1 mg of iron" adequately describes Triferic liquid and is available for assignment by insurers, if they deem appropriate. Use of the JE modifier "administered via dialysate" together with code J1443, addresses the applicant's request to specify use of this product in hemodialysate.	This request to revise existing code J1443 is not approved, because the requested revision does not improve the code. The existing code J1443 "Injection, ferric pyrophosphate citrate solution, 0.1 mg of iron" adequately describes Triferic liquid and is available for assignment by insurers, if they deem appropriate. Use of the JE modifier "administered via dialysate" together with code J1443, addresses the applicant's request to specify use of this product in hemodialysate.
19.082	Request to establish a new Level II HCPCS code to identify Ferric pyrophosphate citrate powder, Trade Name: Triferic powder packet. Applicant's suggested language: JXXXX "Ferric pyrophosphate citrate powder, 0.1 mg of iron in hemodialysate".	Establish new Level II HCPCS code J1444 "Injection, ferric pyrophosphate citrate powder, 0.1 mg of iron", Effective 7/1/19. This code would be used with the existing "JE" modifier"Administered via dialysate", when administered via dialysate.	CMS established new Level II HCPCS code J1444 "Injection, ferric pyrophosphate citrate powder, 0.1 mg of iron", Effective 7/1/19. This code would be used with the existing "JE" modifier"Administered via dialysate", when administered via dialysate.
19.083	Request to establish to a new Level II HCPCS code to identify Glucagon, Trade Name: Glucagon for injection (Fresenius Kabi). Applicant's suggested language: "Injection, Glucagon (Fresenius Kabi), 1 mg"	Existing Multi-source code J1610 "Injection, Glucagon Hydrochloride, per 1 mg" adequately describes the product that is the subject of this application. As Glucagon was coded and marketed prior to October 1, 2003, it is grandfathered and not subject to the separate pricing requirements under section 1847A of the Social Security Act. The NDA approval, by itself, does not establish Glucogan as a sole source product.	Existing Multi-source code J1610 "Injection, Glucagon Hydrochloride, per 1 mg" adequately describes the product that is the subject of this application. As Glucagon was coded and marketed prior to October 1, 2003, it is grandfathered and not subject to the separate pricing requirements under section 1847A of the Social Security Act. The NDA approval, by itself, does not establish Glucogan as a sole source product.
19.085	Request to establish a new Level II HCPCS code to identify romosozumab-aqqg, Trade Name: Evenity. Applicant's suggested language: JXXXX "Injection, romosozumab, 1 mg."	Establish new Level II HCPCS code JXXXX "Injection, romosozumab-aqqg, 1 mg."	CMS established new Level II HCPCS code J3111 "Injection, romosozumab-aqqg, 1 mg". Effective 10/01/2019
19.087	Request to revise existing Level II HCPCS code Q4133 which currently reads: "Grafix prime, grafixpl prime, stravix and stravixpl, per square centimeter", to omit Stravix products, and to instead read: "Grafix PRIME® and GrafixPL PRIME, per square centimeter"; and request to establish a new Level II HCPCS code to identify Stravix and StravixPL. Applicant's suggested language: "QXXXX Stravix, and StravixPL, per square centimeter".	CMS supports its 2018-2019 coding cycle decision honoring Osiris' prior request to include Grafix and Stravix products together in existing code Q4133. Existing code Q4133 "Grafix prime, grafixpl prime, stravix and stravixpl, per square centimeter", adequately describes the Stravix and Grafix products that are subject to this application.	Existing code Q4133 "Grafix prime, grafixpl prime, stravix and stravixpl, per square centimeter", adequately describes the Stravix and Grafix products that are subject to this application.
19.088	Request to establish a single new Level II HCPCS code to identify WoundFix™ Membrane BioWound™ Membrane. Applicant's suggested language: Q41XX WoundFix™ Membrane & BioWound™ Membrane, per square centimeter	Establish Q42XX "Woundfix, Biowound, Woundfix Plus, Biowound Plus, Woundfix Xplus or Biowound Xplus, per square centimeter"	Establish new Level II HCPCS code Q4217 "Woundfix, Biowound, Woundfix Plus, Biowound Plus, Woundfix Xplus or Biowound Xplus, per square centimeter".
19.089	Request to establish a single new Level II HCPCS code to identify human, chorion-based membranes. Trade Names: WoundFix™ Plus Membrane and BioWound™ Plus Membrane Applicant's suggested language: Q41XX WoundFix™ Plus Membrane & BioWound™ Plus Membrane, per square centimeter	Establish Q42XX "Woundfix, Biowound, Woundfix Plus, Biowound Plus, Woundfix Xplus or Biowound Xplus, per square centimeter"	Establish new Level II HCPCS code Q4217 "Woundfix, BioWound, Woundfix Plus, BioWound Plus, Woundfix Xplus or BioWound Xplus, per square centimeter".
19.090	Request to establish a single new Level II HCPCS code to identify human placental tissue based membranes. Trade Names: WoundFix™ XPlus Membrane and BioWound™ XPlus Membrane. Applicant's suggested language: Q41XX WoundFix™ XPlus Membrane & BioWound™ XPlus Membrane, per square centimeter.	Establish Q42XX "Woundfix, Biowound, Woundfix Plus, Biowound Plus, Woundfix Xplus or Biowound Xplus, per square centimeter"	Establish new Level II HCPCS code Q4217 "Woundfix, BioWound, Woundfix Plus, BioWound Plus, Woundfix Xplus or BioWound Xplus, per square centimeter".
19.091	Request to establish a new Level II HCPCS code to identify trastuzumab-dkst, biosimilar, Trade Name: Ogivri. Applicant's suggested language: "Injection, trastuzumab-dkst, biosimilar, (ogivri), 10 mg."	Establish new level II HCPCS code Q5114 "Injection, Trastuzumab-dkst, biosimilar, (Ogivri), 10 mg", Effective 7/1/2019. New code Q5114 will adequately describe Ogivri.	CMS established new level II HCPCS code Q5114 "Injection, Trastuzumab-dkst, biosimilar, (Ogivri), 10 mg", Effective 7/1/2019. New code Q5114 will adequately describe Ogivri.
19.092	Request to establish another Level II HCPCS code to identify Iohexol, Trade Name: Omnipaque. Applicant suggested language: Q99XX "Low osmolar contrast material, 1-99 mg/ml iodine concentration, per ml".	Contrast material is included in the CPT procedure code for CT with contrast. And as such, additional coding will be redundant.	CMS was unable to find policy on the part of any insurance sector that would indicate a need for a code to identify Low osmolar contrast material, 1-99 mg/ml iodine concentration. For coding guidance, please refer to the insurer(s) in whose jurisdiction(s) claim(s) would be filed. For Medicare, contact the Medicare contractor. For Medicaid, contact the Medicaid Agency in the state in which the claims would be filed. For private insurance, contact the individual private insurance entity.

19.093	Request to establish a new Level II HCPCS code to identify Calaspargase pegol-mknl, Trade Name: Asparlas. Applicant's suggested language: "Calaspargase pegol-mknl; 3,750 units/5 mL (750 units/mL)."	Establish new Level II HCPCS code J9XXX "Injection, calaspargase pegol-mknl, 10 units."	CMS established Level II HCPCS code J9118 "Injection, calaspargase pegol-mknl, 10 units". Effective 10/01/2019
19.094	Request to establish a new HCPCS level II code to identify Zulresso (brexanolone) injection 5 mg/ml. Zulresso (brexanolone) injection 5 mg/ml indication for use is postpartum depression. FDA intends to recommend scheduling of Zulresso under the Controlled Substance Act (CSA).	Zulresso is not suitable for coding in Level II HCPCS outside of CMS' pass-through coding process due to setting of use. We refer the applicant to CMS' pass-through program for consideration of coding for reporting use in HOPPS settings. For hospital inpatient use the product is included in the bundled payment.	Zulresso is not suitable for coding in Level II HCPCS outside of CMS' pass-through coding process due to setting of use. For hospital inpatient use the product is included in the bundled payment. Newly established pass-through code C9055 "Injection, brexanolone, 1mg" is available for assignment by insurers, if they deem appropriate to identify hospital outpatient use. For coding guidance contact the insurers in whose jurisdiction claims would be filed.
19.095	Request to revise existing Level II HCPCS code Q4122, which currently reads: "DermACELL, per square centimeter", to instead read: "DermACELL, DermACELL AWM, DermACELL AWM Porous, per square centimeter."	Revise existing code Q4122, which currently reads, "Dermacell, per square centimeter", to instead read "Dermacell, Dermacell Awm or Dermacell Awm Porous, per square centimeter". Revised code Q4122 adequately describes Dermacell, Dermacell Awm or Dermacell Awm Porous, and will be available for assissgnment by insurers if they deem appropriate.	Revise existing code Q4122, which currently reads, "Dermacell, per square centimeter", to instead read "Dermacell, Dermacell Awm or Dermacell Awm Porous, per square centimeter".
19.096	Request to establish a new Levell II HCPCS code to identify Emapalumab-lzsg. Trade Name: Gamifant™. Applicant's suggested language: "Infusion, emapalumab-lzsg injection, for intravenous use, per 1 mg".	Establish new Level II HCPCS code J92XX "Injection, emapalumab-lzsg, 1 mg".	CMS established new Level II HCPCS code J9210 "Injection, emapalumab-lzsg, 1 mg". Effective 10/01/2019.
19.097	Request to establish a new Level II HCPCS code to identify Eravacycline, Trade Name: Xerava. Applicant's suggested language: "Xerava for injection, 50 mg per vial".	Establish new Level II HCPCS code JXXXX "Injection, eravacycline, 1 mg"	CMS established new Level II HCPCS code J0122 "Injection, eravacycline, 1 mg." Effective 10/01/2019
19.098	Request to establish a series of six new Level II HCPCS codes to identify High potency polymerized cross-linked sucralfate (HPPCLS), Trade Name: ProThelial. Applicant's suggested language: "JXXXX Mucositis Paste, 75ml-Polymerized Cross-linked Sucralfate, ProThelial 10%", "JXXXX Mucositis Paste, 120ml-Polymerized Cross-linked Sucralfate, ProThelial 10%", "JXXXX Mucositis Paste, 125ml-Polymerized Cross-linked Sucralfate, ProThelial 10%", "JXXXX Mucositis Paste, 250ml-Polymerized Cross-linked Sucralfate, ProThelial 10%",	Existing NDC codes are available for assignment by all insurers to identify these ProThelial products, if they deem appropriate. As such, adding Level II HCPCS codes would be redundand and unnecessary. Level II HCPCS codes for the purpose of reporting to Medicare on claims in lieu of NDC codes is unnecessary becasue these orally administered products are not reportable under Part B, and they are also not reportable under Part D, because they are not FDA approved as drugs.	CMS was unable to find policy on the part of any insurance sector that would indicate a need for a code to identify mucositis paste, polymerized cross linked sucralfate. For coding guidance, please refer to the insurer(s) in whose jurisdiction(s) claim(s) would be filed. For Medicare, contact the Medicare contractor. For Medicaid, contact the Medicaid Agency in the state in which the claims would be filed. For private insurance, contact the individual private insurance entity.
19.099	Request to establish a new Level II HCPCS code to identify a human umbilical tissue membrane allograft, Trade Name: SurgiCORD. Applicant's suggested language: QXXXX "SurgiCORD per sq. cm".	Establish Q42XX "Surgicord, per square centimeter"	Establish new Level II HCPCS code Q4218 "Surgicord, per square centimeter".
19.100	Request to establish a new Level II HCPCS code to identify a bilayer human amniotic tissue allograft, Trade Name: SurgiGRAFT-DUAL Applicant's suggested language: QXXXX "SurgiGRAFT-DUAL per sq. cm".	Establish Q42XX "Surgigraft-dual, per square centimeter"	Establish new Level II HCPCS code Q4219 "Surgigraft-dual, per square centimeter".
19.101	Request to establish a new Level II HCPCS code to identify an Amniotic/Chorionic Tissue Allograft, Trade Name: AmnioWrap2.	Establish Q42XX "Amniowrap2, per square centimeter"	Establish new Level II HCPCS code Q4221 "Amniowrap2, per square centimeter".
19.102	Request to establish a new Level II HCPCS code to identify a plastic vessel to regulate the flow of urine. Trade name: BioFlo Auto Valve. Applicant's suggested language: "Vessel containing an automated release mechanism to regulate the flow of urine"	Anti-reflux capability is included in existing code A4357 "Bedside drainage bag, day or night, with or without anti-reflux device, with or without tube, each". Existing code A9900 "Miscellaneous dme supply, accessory, and/or service component of another hcpcs code" is also available for assignment by insurers, if they deem appropriate. We do not have information from any insurer that a coding distinction to specify "auto-release" release feature is needed. The Level II HCPCS codes describe categories of similar items. The code set is not intended to be an exhaustive listing of all products on the market. While CMS believes that existing codes, as indicated above, describe the products that are the subject of this request, as a general rule, CMS does not assign individual products to existing codes on behalf of any insurer. Individual insurers have the necessary flexibility to assign individual products to existing codes in the manner consistent with their individual policies and programmatic needs. For coding guidance, please refer to the insurer(s) in whose jurisdiction(s) claim would be filed. For Medicaid, contact the Medicaid Agency in the state in which the claims would be filed. For private insurance, contact the individual private insurance entity. Under contract to CMS, the Pricing, Data Analysis and Coding (PDAC) provides coding verifications for the purpose of billing Medicare. For confirmation of appropriate code assignment for Medicare billing, you may contact the PDAC Contact Center toll free at 877-735-1326. For your convenience, the PDAC has compiled a product classification system called DMECS that lists individual products by brand name under code categories. This system is available at: http://www.dmepdac.com. If you do not find your product listed by the PDAC matrix, you may request a coding verification for your product by contacting the PDAC at the toll free telephone number listed above.	Anti-reflux capability is included in existing code A4357 "Bedside drainage bag, day or night, with or without anti-reflux device, with or without tube, each". Existing code A9900 "Miscellaneous dme supply, accessory, and/or service component of another hcpcs code" is also available for assignment by insurers, if they deem appropriate. We do not have information from any insurer that a coding distinction to specify "auto-release" release feature is needed. The Level II HCPCS codes describe categories of similar items. The code set is not intended to be an exhaustive listing of all products on the market. While CMS believes that existing codes, as indicated above, describe the products that are the subject of this request, as a general rule, CMS does not assign individual products to existing codes on behalf of any insurer. Individual insurers have the necessary flexibility to assign individual products to existing codes in the manner consistent with their individual policies and programmatic needs. For coding guidance, please refer to the insurer(s) in whose jurisdiction(s) claim would be filed. For Medicaid, contact the Medicaid Agency in the state in which the claims would be filed. For private insurance, contact the individual private insurance entity. Under contract to CMS, the Pricing, Data Analysis and Coding (PDAC) provides coding verifications for the purpose of billing Medicare. For confirmation of appropriate code assignment for Medicare billing, you may contact the PDAC Contact Center toll free at 877-735-1326. For your convenience, the PDAC has compiled a product classification system called DMECS that lists individual products by brand name under code categories. This system is available at: http://www.dmepdac.com. If you do not find your product listed by the PDAC matrix, you may request a coding verification for your product by contacting the PDAC at the toll free telephone number listed above.
19.104	Request to establish a new Level II HCPCS code to identify the Computer Based Training for Cognitive Behavioral Therapy. Trade name: CBT4CBT	This request to establish a Level II HCPCS codes to identify CBT4CBT computer based training has not been approved, because this product is not primarily medical in nature. To the extent there is practitioner involvement in this training with the self-help/training system, CMS refers the applicant to the American Medical Association (AMA) for CPT coding guidance	CMS has given considerable thought to this request to establish a code to identify computer based trainig for cognitive behavior. CMS has not identified policy or claims processing need on the part of any insurance sector for code to identify self-guided training program on the claim. We understand that self-help web-based software treatment and self-help devices are an important and emerging science. It is our understandign that Food and Drug Administration and American Medical assoc are reviewing this technology in detail as they consider product and procedure classification. Please contact me personally at my e-mail: cynthia.hake@cms.hhs.gov, for directr referral within an AMA. CMS would also like to refer you to the insuresr in which jurisdiction claims would be filed for coding guidance.

19.105	Request to establish a new Level II HCPCS code to identify an endotracheal tube holder with foam strap and silicone bite block combination. Trade name: Haider Tube Guard.	This request to establish a code, to separately identify the Haider Tube guard for use in endotracheal intubation during surgery, is not suitable for coding in HCPCS Level II outside of pass-through codes. A request for separate identification of this product for hospital outpatient use maybe be made to CMS' pass-through application process.	This request to establish a code, to separately identify the Haider Tube guard for use in endotracheal intubation during surgery, is not suitable for coding in HCPCS Level II outside of pass-through codes. A request for separate identification of this product for hospital outpatient use maybe be made to CMS' pass-through application process.
19.106	Request to establish a new Level II HCPCS code to identify a surgical nail splint for the reconstructive surgery of the nail bed. Trade name: INRO Surgical Nail.	The INRO Surgical Nail is an integral part of a surgical procedure. CMS refers the applicant to the American Medical Association (AMA) for coding guidance for reporting use in conjunction with avulsion surgery.	The INRO Surgical Nail is an integral part of a surgical procedure. CMS refers the applicant to the American Medical Association (AMA) for coding guidance for reporting use in conjunction with avulsion surgery.
19.107	Request to establish a new Level II HCPCS code to identify a single use device which is fixed to a transrectal ultrasound probe. Trade name: PrecisionPoint Transperineal Access System. Applicant's suggested language: "PrecisionPoint Transperineal	This request to establish a new code to separately identify PrecisionPoint Transperineal Access System (PPTAS), has not been approved. PPTAS is an integral part of a procedure. PPTAS, if used, is included in the procedure, and separate coding could be construed as redundant.	This request to establish a new code to separately identify PrecisionPoint Transperineal Access System (PPTAS), has not been approved. CMS refers the applicant to the American Medical Association (AMA) for consideration of CPT coding performing the service using the transperineal approach using this or other similar devices.
19.108	Request to establish a new Level II HCPCS code to identify an ostomy smart post-operative starter kit for new patients after surgery. Trade name: Alfred Smart Post-Operative Kit. Applicant's suggested language: AXXXX Ostomy Smart Post-Operative Kit containing 4 Alfred SmartBags and 1 Alfred SmartWafer, each.	The Alfred Smart Post-Operative Kit is used for new patients in the hospital setting following the surgery and prior to hospital discharge. As such, if used, it is included in the hospital payment. It is not suitable for coding in HCPCS Level II, and separate reporting may be redundant.	The Alfred Smart Post-Operative Kit is used for new patients in the hospital setting following the surgery and prior to hospital discharge. As such, if used, it is included in the hospital payment. It is not suitable for coding in HCPCS Level II, and separate reporting may be redundant.
19.109	Request to establish a new Level II HCPCS code to identify a 30 -day supply of ostomy bags and wafers. Trade name: Alfred Smart 30 day Kit. Applicant's suggested language: AXXXX "Ostomy Smart 30 Day Kit."	The Level II HCPCS codes describe categories of similar items. The code set is not intended to be an exhaustive listing of all products on the market. While CMS believes that existing codes, as indicated above, describe the products that are the subject of this request, as a general rule, CMS does not assign individual products to existing codes on behalf of any insurer. Individual insurers have the necessary flexibility to assign individual products to existing codes in the manner consistent with their individual policies and programmatic needs. For coding guidance, please refer to the insurer(s) in whose jurisdiction(s) claim would be filed. For Medicaid, contact the Medicaid Agency in the state in which the claims would be filed. For private insurance, contact the individual private insurance entity. Under contract to CMS, the Pricing, Data Analysis and Coding (PDAC) provides coding verifications for the purpose of billing Medicare. For confirmation of appropriate code assignment for Medicare billing, you may contact the PDAC Contact Center toll free at 877-735-1326. For your convenience, the PDAC has compiled a product classification system called DMECS that lists individual products by brand name under code categories. This system is available at: http://www.dmepdac.com. If you do not find your product listed by the PDAC matrix, you may request a coding verification for your product by contacting the PDAC at the toll free telephone number listed above.	The Level II HCPCS codes describe categories of similar items. The code set is not intended to be an exhaustive listing of all products on the market. While CMS believes that existing codes describe the products in the kit A4426, "Ostomy pouch, drainable; for use on barrier with locking flange (2 piece system), each" describes the pouch; A4409, "Ostomy skin barrier, with flange (solid, flexible or accordion), extended wear, without built-in convexity, 4 x 4 inches or smaller, each", or A4410, "Ostomy skin barrier, with flange (solid, flexible or accordion), extended wear, without built-in convexity, larger than 4 x 4 inches, each", (depending on size) describes the wafer; and A9279, " Monitoring feature/device, stand-alone or integrated, any type, includes all accessories, components and electronics, not otherwise classified", describes the monitoring component, as a general rule, CMS doesn't assign individual products to existing codes on behalf of any insurer. Individual insurers have the necessary flexibility to assign individual products to existing codes in the manner consistent with their individual policies and programmatic needs. For coding guidance please refer to the insurer(s) in whose jurisdiction(s) claims would be filed. For Medicaid, contact the Medicaid agency in the state in which the claim would be filed. For private insurance, contact the individual private insurance entity.
19.110	Request to establish a new Level II HCPCS code to identify an ostomy supply. Trade name: Alfred SmartBag. Applicant's suggested language: AXXXX Ostomy smart pouch, drainable, opaque, with sensors, without barrier, each.	Existing code A4420 "Ostomy pouch, closed; for use on barrier with locking flange (2 piece), each" adequately describes the ostomy pouch component of the ostomy smart pouch and existing code A9279 "Monitoring feature/device, stand-alone or integrated, any type, includes all accessories, components and electronics, not otherwise classified" adequately describes the monitoring component of the ostomy smart pouch. The Level II HCPCS codes describe categories of similar items. The code set is not intended to be an exhaustive listing of all products on the market. While CMS believes that existing codes, as indicated above, describe the products that are the subject of this request, as a general rule, CMS does not assign individual products to existing codes on behalf of any insurer. Individual insurers have the necessary flexibility to assign individual products to existing codes in the manner consistent with their individual policies and programmatic needs. For coding guidance, please refer to the insurer(s) in whose jurisdiction(s) claim would be filed. For Medicaid, contact the Medicaid Agency in the state in which the claims would be filed. For private insurance, contact the individual private insurance entity. Under contract to CMS, the Pricing, Data Analysis and Coding (PDAC) provides coding verifications for the purpose of billing Medicare. For confirmation of appropriate code assignment for Medicare billing, you may contact the PDAC Contact Center toll free at 877-735-1326. For your convenience, the PDAC has compiled a product classification system called DMECS that lists individual products by brand name under code categories. This system is available at: http://www.dmepdac.com. If you do not find your product listed by the PDAC matrix, you may request a coding verification for your product by contacting the PDAC at the toll free telephone number listed above.	Existing code A4426 "Ostomy pouch, drainable; for use on barrier with locking flange (2 piece system), each" adequately describes the ostomy pouch component of the ostomy smart pouch and existing code A9279 "Monitoring feature/device, stand-alone or integrated, any type, includes all accessories, components and electronics, not otherwise classified" adequately describes the monitoring component of the ostomy smart pouch. The Level II HCPCS codes describe categories of similar items. The code set is not intended to be an exhaustive listing of all products on the market. While CMS believes that existing codes, as indicated above, describe the products that are the subject of this request, as a general rule, CMS does not assign individual products to existing codes on behalf of any insurer. Individual insurers have the necessary flexibility to assign individual products to existing codes in the manner consistent with their individual policies and programmatic needs. For coding guidance, please refer to the insurer(s) in whose jurisdiction(s) claim would be filed. For Medicaid, contact the Medicaid Agency in the state in which the claims would be filed. For private insurance, contact the individual private insurance entity. Under contract to CMS, the Pricing, Data Analysis and Coding (PDAC) provides coding verifications for the purpose of billing Medicare. For confirmation of appropriate code assignment for Medicare billing, you may contact the PDAC Contact Center toll free at 877-735-1326. For your convenience, the PDAC has compiled a product classification system called DMECS that lists individual products by brand name under code categories. This system is available at: http://www.dmepdac.com. If you do not find your product listed by the PDAC matrix, you may request a coding verification for your product by contacting the PDAC at the toll free telephone number listed above.

19.111	Request to establish a new Level II HCPCS code to identify a programmed microprocessor which translates data for a continuous monitoring ostomy system. Trade name: Alfred SmartHub. Applicant's suggested language: AXXXX, Programmed microprocessor translates data for a continuous monitoring ostomy system, each.	Existing code A9279 "Monitoring feature/device, stand-alone or integrated, any type, includes all accessories, components and electronics, not otherwise classified" adequately describes the monitoring feature of the Alfred SmartHub, and is available for assignment by insurers if they deem appropriate. The Level II HCPCS codes describe categories of similar items. The code set is not intended to be an exhaustive listing of all products on the market. While CMS believes that an existing code, as indicated above, describes the product that is the subject of this request, as a general rule, CMS does not assign individual products to existing codes on behalf of any insurer. Individual insurers have the necessary flexibility to assign individual products to existing codes in the manner consistent with their individual policies and programmatic needs. For coding guidance, please refer to the insurer(s) in whose jurisdiction(s) claim would be filed. For Medicaid, contact the Medicaid Agency in the state for which the claims would be filed. For private insurance, contact the individual private insurance entity. Under contract to CMS, the Pricing, Data Analysis and Coding (PDAC) provides coding verifications for the purpose of billing Medicare. For confirmation of appropriate code assignment for Medicare billing, you may contact the PDAC Contact Center toll free at 877-735-1326. For your convenience, the PDAC has compiled a product classification system called DMECS that lists individual products by brand name under code categories. This system is available at: http://www.dmepdac.com. If you do not find your product listed by the PDAC matrix, you may request a coding verification for your product by contacting the PDAC at the toll free telephone number listed above.	Existing code A9279 "Monitoring feature/device, stand-alone or integrated, any type, includes all accessories, components and electronics, not otherwise classified", adequately describes the monitoring feature of the Alfred SmartHub, and is available for assignment by insurers if they deem appropriate. The Level II HCPCS codes describe categories of similar items. The code set is not intended to be an exhaustive listing of all products on the market. While CMS believes that an existing code, as indicated above, describes the product that is the subject of this request, as a general rule, CMS does not assign individual products to existing codes on behalf of any insurer. Individual insurers have the necessary flexibility to assign individual products to existing codes in the manner consistent with their individual policies and programmatic needs. For coding guidance, please refer to the insurer(s) in whose jurisdiction(s) claim would be filed. For Medicaid, contact the Medicaid Agency in the state in which the claims would be filed. For private insurance, contact the individual private insurance entity. Under contract to CMS, the Pricing, Data Analysis and Coding (PDAC) provides coding verifications for the purpose of billing Medicare. For confirmation of appropriate code assignment for Medicare billing, you may contact the PDAC Contact Center toll free at 877-735-1326. For your convenience, the PDAC has compiled a product classification system called DMECS that lists individual products by brand name under code categories. This system is available at: http://www.dmepdac.com. If you do not find your product listed by the PDAC matrix, you may request a coding verification for your product by contacting the PDAC at the toll free telephone number listed above. Effective 01/01/2020
19.112	Request to establish a new Level II HCPCS code to identify a sheet mounted with an array of thermistor sensors, an NFC (Near Field Communication) antenna and a battery. Trade name: Alfred SmartWafer. Applicant's suggested language: AXXXX Skin barrier/wafer, 3.7in by 4.37in, hydrocolloid flat sheet with an array of thermistors, each.	Existing code A4409 "Ostomy skin barrier, with flange (solid, flexible or accordion), extended wear, without built-in convexity, 4 x 4 inches or smaller, each" or A4410 "Ostomy skin barrier, with flange (solid, flexible or accordion), extended wear, without built-in convexity, larger than 4 x 4 inches, each " adequately describes the skin barrier function of this Alfred SmartWafer, and is available for assignment by insurers if they deem appropriate. Existing code A9279 "Monitoring feature/device, stand-alone or integrated, any type, includes all accessories, components and electronics, not otherwise classified" adequately describes the sensor array monitoring feature of the Alfred SmartWafer. The Level II HCPCS codes describe categories of similar items. The code set is not intended to be an exhaustive listing of all products on the market. While CMS believes that existing codes, as indicated above, describe the products that are the subject of this request, as a general rule, CMS does not assign individual products to existing codes on behalf of any insurer. Individual insurers have the necessary flexibility to assign individual products to existing codes in the manner consistent with their individual policies and programmatic needs. For coding guidance, please refer to the insurer(s) in whose jurisdiction(s) claim would be filed. For Medicaid, contact the Medicaid Agency in the state in which the claims would be filed. For private insurance, contact the individual private insurance entity. Under contract to CMS, the Pricing, Data Analysis and Coding (PDAC) provides coding verifications for the purpose of billing Medicare. For confirmation of appropriate code assignment for Medicare billing, you may contact the PDAC Contact Center toll free at 877-735-1326. For your convenience, the PDAC has compiled a product classification system called DMECS that lists individual products by brand name under code categories. This system is available at: http://www.dmepdac.com. If you do not find your product listed by the PDAC matrix, you may request a coding verification for your product by contacting the PDAC at the toll free telephone number listed above.	Existing code A4409 "Ostomy skin barrier, with flange (solid, flexible or accordion), extended wear, without built-in convexity, 4 x 4 inches or smaller, each" or A4410 "Ostomy skin barrier, with flange (solid, flexible or accordion), extended wear, without built-in convexity, larger than 4 x 4 inches, each", (depending on size) adequately describes the skin barrier function of this Alfred SmartWafer, and are available for assignment by insurers if they deem appropriate. Existing code A9279 "Monitoring feature/device, stand-alone or integrated, any type, includes all accessories, components and electronics, not otherwise classified" adequately describes the sensor array monitoring feature of the Alfred SmartWafer. Effective 01/01/2020
19.113	Request to establish a new Level II HCPCS code to describe a 100% native Type 1 bovine collagen powder for use in wound management, Trade Name: ACM Surgical Extra Advanced Collagen Powder. Applicants suggested language: QXXXX "ACM Surgical Extra Advance Collagen Powder, per gm"	Existing code A6010 "Collagen based wound filler, dry form, sterile, per gram of collagen", adequately describes ACM surgical extra advanced collagen powder and is available for assignment by insures if they deem appropriate.	Existing code A6010 "Collagen based wound filler, dry form, sterile, per gram of collagen", adequately describes ACM surgical extra advanced collagen powder and is available for assignment by insures if they deem appropriate.

| 19.114 | Request to establish a new Level II HCPCS code to identify a cane swing with articulating system and ergonomic handgrip. | Existing codes E0100 "Cane, includes canes of all materials, adjustable or fixed, with tip" and E0105 "Cane, quad or three prong, includes canes of all materials, adjustable or fixed, with tips", are available for assignment by insures if they deem appropriate to describe the Cane Swing. The applicant submitted insufficient evidence to support a claim of significant therapeutic distinction when the cane swing with articulating system is used, compared with use of other canes currently coded included in code categories E0100 or E0105. Shock absorption and articulation are not new technology. A difference in mechanism of operation by itself does not warrant a separate code. These codes are available for assignment by insurers if they deem appropriate.

The Level II HCPCS codes describe categories of similar items. The code set is not intended to be an exhaustive listing of all products on the market. While CMS believes that existing codes, as indicated above, describe the products that are the subject of this request, as a general rule, CMS does not assign individual products to existing codes on behalf of any insurer. Individual insurers have the necessary flexibility to assign individual products to existing codes in the manner consistent with their individual policies and programmatic needs. For coding guidance, please refer to the insurer(s) in whose jurisdiction(s) claim would be filed. For Medicaid, contact the Medicaid Agency in the state in which the claims would be filed. For private insurance, contact the individual private insurance entity.

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There is also insufficient evidence to substantiate the applicant's claim of reduction in falls attributed to use of the proprietary swing link system.

The Level II HCPCS codes describe categories of similar items. The code set is not intended to be an exhaustive listing of all products on the market. While CMS believes that existing codes, as indicated above, describe the products that are the subject of this request, as a general rule, CMS does not assign individual products to existing codes on behalf of any insurer. Individual insurers have the necessary flexibility to assign individual products to existing codes in the manner consistent with their individual policies and programmatic needs. For coding guidance, please refer to the insurer(s) in whose jurisdiction(s) claim would be filed. For Medicaid, contact the Medicaid Agency in the state in which the claims would be filed. For private insurance, contact the individual private insurance entity. Under contract to CMS, the Pricing, Data Analysis and Coding (PDAC) provides coding verifications for the purpose of billing Medicare. For confirmation of appropriate code assignment for Medicare billing, you may contact the PDAC Contact Center toll free at 877-735-1326. For your convenience, the PDAC has compiled a product classification system called DMECS that lists individual products by brand name under code categories. This system is available at: http://www.dmepdac.com. If you do not find your product listed by the PDAC matrix, you may request a coding verification for your product by contacting the PDAC at the toll free telephone number listed above. |
| 19.115 | Request to establish a new Level II HCPCS code to identify an Axilla crutch, Sport and Pro Series. | The applicant did not submit sufficient evidence to support a claim of significant therapeutic distinction for the Swing Lock articulating system when compared with use of underarm crutches currently included in existing code category E0117 "Crutch, underarm, articulating, spring assisted, each". Shock absorption and articulation are existing technology and the difference in mechanism of operation by itself does not warrant a separate code in accordance with CMS' coding decision criteria. Other features mentioned by the applicant such as axilla design in SwingLink feature and the claim of their benefits also have not been substantiated by clinical evidence. Existing code E0117 is available for assignment by insurers if they deem appropriate to describe the Swing Lock.

The Level II HCPCS codes describe categories of similar items. The code set is not intended to be an exhaustive listing of all products on the market. While CMS believes that an existing code, as indicated above, describes the product that is the subject of this request, as a general rule, CMS does not assign individual products to existing codes on behalf of any insurer. Individual insurers have the necessary flexibility to assign individual products to existing codes in the manner consistent with their individual policies and programmatic needs. For coding guidance, please refer to the insurer(s) in whose jurisdiction(s) claim would be filed. For Medicaid, contact the Medicaid Agency in the state in which the claims would be filed. For private insurance, contact the individual private insurance entity.

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These codes are available for assignment by insurers if they deem appropriate. While the CMS maintains the Level II HCPCS code set, it does not assign individual products to existing codes on behalf of any insurer. Individual insurers have the necessary flexibility to assign individual products to existing codes in the manner consistent with their individual policies and programmatic needs. For coding guidance, please refer to the insurer(s) in whose jurisdiction(s) claim would be filed. For Medicare, contact the Medicare contractor. For Medicaid, contact the Medicaid Agency in the state in which the claim would be filed. For private insurance, contact the individual private insurance entity. | The applicant did not submit sufficient evidence to support a claim of significant therapeutic distinction or reduction in falls attributed to use of proprietary use of SwingLink system, when compared with use of underarm crutches currently included in existing code category E0117 "Crutch, underarm, articulating, spring assisted, each". Shock absorption and articulation are existing technology and the difference in mechanism of operation by itself does not warrant a separate code in accordance with CMS' coding decision criteria. Other features mentioned by the applicant such as axilla design in SwingLink feature and the claim of their benefits also have not been substantiated by clinical evidence. Existing code E0117 is available for assignment by insurers if they deem appropriate to describe the Swing Lock.

The Level II HCPCS codes describe categories of similar items. The code set is not intended to be an exhaustive listing of all products on the market. While CMS believes that an existing code, as indicated above, describes the product that is the subject of this request, as a general rule, CMS does not assign individual products to existing codes on behalf of any insurer. Individual insurers have the necessary flexibility to assign individual products to existing codes in the manner consistent with their individual policies and programmatic needs. For coding guidance, please refer to the insurer(s) in whose jurisdiction(s) claim would be filed. For Medicaid, contact the Medicaid Agency in the state in which the claims would be filed. For private insurance, contact the individual private insurance entity.

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| 19.116 | Request to establish a new Level II HCPCS code to identify an adjustable forearm crutch (with plastic cuff). | Existing code E0110 "Crutches, forearm, includes crutches of various materials, adjustable or fixed, pair, complete with tips and handgrips " or E0111 "Crutch forearm, includes crutches of various materials, adjustable or fixed, each, with tip and handgrips" depending on whether each or pair adequately describes versa swing with waist link articulating system that is the subject of this request. Articulating forearm crutches are included in the array of products in code functional categories E0110 and E0111. In addition, these codes are all inclusive of bases /feet of the crutches as well as the arms grips. The applicant confirms in the application that versa swings are "designed to function similarly to forearm cuff crutches."

The Level II HCPCS codes describe categories of similar items. The code set is not intended to be an exhaustive listing of all products on the market. While CMS believes that existing codes, as indicated above, describe the products that are the subject of this request, as a general rule, CMS does not assign individual products to existing codes on behalf of any insurer. Individual insurers have the necessary flexibility to assign individual products to existing codes in the manner consistent with their individual policies and programmatic needs. For coding guidance, please refer to the insurer(s) in whose jurisdiction(s) claim would be filed. For Medicaid, contact the Medicaid Agency in the state in which the claims would be filed. For private insurance, contact the individual private insurance entity.

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The Level II HCPCS codes describe categories of similar items. The code set is not intended to be an exhaustive listing of all products on the market. While CMS believes that existing codes, as indicated above, describe the products that are the subject of this request, as a general rule, CMS does not assign individual products to existing codes on behalf of any insurer. Individual insurers have the necessary flexibility to assign individual products to existing codes in the manner consistent with their individual policies and programmatic needs. For coding guidance, please refer to the insurer(s) in whose jurisdiction(s) claim would be filed. For Medicaid, contact the Medicaid Agency in the state in which the claims would be filed. For private insurance, contact the individual private insurance entity.

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		This system is available at: http://www.dmepdac.com. If you do not find your product listed by the PDAC matrix, you may request a coding verification for your product by contacting the PDAC at the toll free telephone number listed above.	compiled a product classification system called DMECS that lists individual products by brand name under code categories. This system is available at: http://www.dmepdac.com. If you do not find your product listed by the PDAC matrix, you may request a coding verification for your product by contacting the PDAC at the toll free telephone number listed above.
19.117	Request to establish a new Level II HCPCS code to identify the Alpha-Stim Cranial Electrotherapy Stimulation (CES) system, Trade Name: Alpha-Stim AID. Applicant's suggested language: EXXXX "Cranial Electrotherapy Stimulation (CES) starter kit (includes CES device, ear clip electrodes, electrode pads, conductive solution)."	Establish new code EXXXX "Cranial electrotherapy stimulation (CES) system, includes all supplies and accessories, any type."	Establish new code EXXXX Level II HCPCS code K1002 "Cranial electrotherapy stimulation (CES) system, includes all supplies and accessories, any type." Effective 1/1/2020
19.118	Request to establish a new Level II HCPCS code to identify sleep position therapy device, Trade Name: Lunoa system. Applicant's suggested language: EXXXX "Sleep position therapy device, electronic sensor with adjustable vibrotactile feedback, includes all components."	Existing Level II HCPCS code A9279 "Monitoring feature/device, stand-alone or integrated, any type, includes all accessories, components and electronics, not otherwise classified", describes the monitoring features of the Lunoa system sleep position training, monitoring sensing system, and is available for assignment by insurers if they deem appropriate. Existing code A9280 "Alert or alarm device, not otherwise classified" is available for assignment by insurers if they deem appropriate to describe the "vibrational feedback" provided by the Lunoa system.	Establish a new Level II HCPCS code K1001 "Electronic positional obstructive sleep apnea treatment, with sensor, includes all components and accessories, any type". Effective 01/01/2020
19.119	Request to establish a new Level II HCPCS code to identify the Precice External Remote Controller for patient use as part of their post-operative limb-lengthening protocol.	The ERC Controller is initially issued post surgery prior to patient discharge. As such, it is included in the hospital payment. If used during a specific HOPD or ASC procedure/service, payment would be included in the CPT code that is reported. Separate billing would be redundant.	The ERC Controller is initially issued post surgery prior to patient discharge. As such, it is included in the hospital payment. If used during a specific HOPD or ASC procedure/service, payment would be included in the CPT code that is reported. Separate billing would be redundant.
19.120	Request to establish a new Level II HCPCS code to identify Wheelchair Accessory, Trade Name: Sunrise Medical Dynamic Seating Component. Applicant suggested language: EXXX1 "wheelchair accessory, dynamic seating (seat to back or pelvis) component."	Establish EXXXX: "Wheelchair accessory, dynamic positioning hardware for back"	Establish a new Level II HCPCS code E2398 "Wheelchair accessory, dynamic positioning hardware for back" Effective 1/1/2019
19.121	Request to establish two new Level II HCPCS codes to identify components of an integrated real-time system continuous glucose monitoring system, Trade Name: Dexcom G6 continuous glucose monitoring system. Applicant's suggested language: EXXXX "Receiver (monitor) dedicated, for use with continuous glucose monitor." EXXXX "supply allowance for integrated continuous glucose monitor (CGM), includes all supplies and accessories, 1 unit of service=1 month's supply."	Establish new code EXXXX "External ambulatory infusion pump, insulin, dosage rate adjustment using therapeutic continuous glucose sensing". Establish new code AXXXX "Supplies for maintenance of insulin infusion pump with dosage rate adjustment using therapeutic continuous glucose sensing, per week"	Existing codes K0553, "Supply allowance for therapeutic continuous glucose monitor (cgm), includes all supplies and accessories, 1 month supply = 1 unit of service", and K0554, "Receiver (monitor), dedicated, for use with therapeutic glucose continuous monitor system" adequately describe the subject of this application. Effective 01/01/2020
19.123	Request to establish a new Level II HCPCS code to identify a self guided exercising device of the hand, including wrist and fingers, Trade Name: RAPAEL Smart Glove for Home. Applicant's suggested language: EXXXX "Self-guided exercising device of the hand, including wrist and fingers, using hand mounted device with software contents enabling real-time measurement and monitoring of hand movements."	Existing code A9300 "Exercise Equipment", adequately describes the RAPAEL Smart Glove and is available for assignment by insurers if they deem appropriate. The Level II HCPCS codes describe categories of similar items. The code set is not intended to be an exhaustive listing of all products on the market. While CMS believes that an existing code, as indicated above, describes the product that is the subject of this request, as a general rule, CMS does not assign individual products to existing codes on behalf of any insurer. Individual insurers have the necessary flexibility to assign individual products to existing codes in the manner consistent with their individual policies and programmatic needs. For coding guidance, please refer to the insurer(s) in whose jurisdiction(s) claim would be filed. For Medicaid, contact the Medicaid Agency in the state in which the claims would be filed. For private insurance, contact the individual private insurance entity. Under contract to CMS, the Pricing, Data Analysis and Coding (PDAC) provides coding verifications for the purpose of billing Medicare. For confirmation of appropriate code assignment for Medicare billing, you may contact the PDAC Contact Center toll free at 877-735-1326. For your convenience, the PDAC has compiled a product classification system called DMECS that lists individual products by brand name under code categories. This system is available at: http://www.dmepdac.com. If you do not find your product listed by the PDAC matrix, you may request a coding verification for your product by contacting the PDAC at the toll free telephone number listed above.	Existing code A9300 "Exercise Equipment", adequately describes the RAPAEL Smart Glove and is available for assignment by insurers if they deem appropriate. The Level II HCPCS codes describe categories of similar items. The code set is not intended to be an exhaustive listing of all products on the market. While CMS believes that an existing code, as indicated above, describes the product that is the subject of this request, as a general rule, CMS does not assign individual products to existing codes on behalf of any insurer. Individual insurers have the necessary flexibility to assign individual products to existing codes in the manner consistent with their individual policies and programmatic needs. For coding guidance, please refer to the insurer(s) in whose jurisdiction(s) claim would be filed. For Medicaid, contact the Medicaid Agency in the state in which the claims would be filed. For private insurance, contact the individual private insurance entity. Under contract to CMS, the Pricing, Data Analysis and Coding (PDAC) provides coding verifications for the purpose of billing Medicare. For confirmation of appropriate code assignment for Medicare billing, you may contact the PDAC Contact Center toll free at 877-735-1326. For your convenience, the PDAC has compiled a product classification system called DMECS that lists individual products by brand name under code categories. This system is available at: http://www.dmepdac.com. If you do not find your product listed by the PDAC matrix, you may request a coding verification for your product by contacting the PDAC at the toll free telephone number listed above.

19.124	Request to establish a Level II HCPCS code to identify suspension and vibration reduction propulsion wheels, Trade Name: Loopwheels. Applicant's suggested language: "Manual wheelchair accessory, vibration reducing and suspension propulsion wheel, excludes tire, any size, each."	The suspension and vibration reduction propulsion wheels that are the subject of this request are included in the wheelchair base code on initial issue. Existing code E2224 "Manual wheelchair accessory, propulsion wheel excludes tire, any size, replacement only, each" adequately describes replacement propulsion wheels, and is available for assignment by insurers if they deem appropriate. The Level II HCPCS codes describe categories of similar items. The code set is not intended to be an exhaustive listing of all products on the market. While CMS believes that existing codes, as indicated above, describe the product that is the subject of this request, as a general rule, CMS does not assign individual products to existing codes on behalf of any insurer. Individual insurers have the necessary flexibility to assign individual products to existing codes in the manner consistent with their individual policies and programmatic needs. For coding guidance, please refer to the insurer(s) in whose jurisdiction(s) claim would be filed. For Medicaid, contact the Medicaid Agency in the state in which the claims would be filed. For private insurance, contact the individual private insurance entity. Under contract to CMS, the Pricing, Data Analysis and Coding (PDAC) provides coding verifications for the purpose of billing Medicare. For confirmation of appropriate code assignment for Medicare billing, you may contact the PDAC Contact Center toll free at 877-735-1326. For your convenience, the PDAC has compiled a product classification system called DMECS that lists individual products by brand name under code categories. This system is available at: http://www.dmepdac.com. If you do not find your product listed by the PDAC matrix, you may request a coding verification for your product by contacting the PDAC at the toll free telephone number listed above.	The suspension and vibration reduction propulsion wheels that are the subject of this request are included in the wheelchair base code on initial issue. Existing code E2224 "Manual wheelchair accessory, propulsion wheel excludes tire, any size, replacement only, each" adequately describes replacement propulsion wheels, and is available for assignment by insurers if they deem appropriate. The Level II HCPCS codes describe categories of similar items. The code set is not intended to be an exhaustive listing of all products on the market. While CMS believes that existing codes, as indicated above, describe the product that is the subject of this request, as a general rule, CMS does not assign individual products to existing codes on behalf of any insurer. Individual insurers have the necessary flexibility to assign individual products to existing codes in the manner consistent with their individual policies and programmatic needs. For coding guidance, please refer to the insurer(s) in whose jurisdiction(s) claim would be filed. For Medicaid, contact the Medicaid Agency in the state in which the claims would be filed. For private insurance, contact the individual private insurance entity. Under contract to CMS, the Pricing, Data Analysis and Coding (PDAC) provides coding verifications for the purpose of billing Medicare. For confirmation of appropriate code assignment for Medicare billing, you may contact the PDAC Contact Center toll free at 877-735-1326. For your convenience, the PDAC has compiled a product classification system called DMECS that lists individual products by brand name under code categories. This system is available at: http://www.dmepdac.com. If you do not find your product listed by the PDAC matrix, you may request a coding verification for your product by contacting the PDAC at the toll free telephone number listed above.
19.125	Request to establish a new Level II HCPCS code to identify Surface Acoustic Waves 90KHz Pain Management Ultra Sound, Trade Name: The PainShield MD.	CMS refers the applicant to the American Medical Association (AMA) for coding guidance for diathermy treatment performed incident to a physician's service. CMS is not aware of a claims processing need on the part of any insurance sector to report self-administered diathermy by patients in their home.	Establish new Level II HCPCS code K1004 "Low frequency ultrasonic diathermy treatment device for home use, includes all components and accessories". Effective 01/01/2020
19.126	Request to establish a new Level II HCPCS code to identify an insulin Pen Injector with Dose Calculator, Trade Name: InPen. Applicant's suggested language: "Connected Insulin Pen with Dose Calculator."	Existing code S5561, "Insulin delivery device, reusable pen; 3 ml size", or A4211, "Supplies for self-administered injections" are available for assignments by insurers to describe the pen and/or dosage calculator application, if they deem appropriate. The Level II HCPCS codes describe categories of similar items. The code set is not intended to be an exhaustive listing of all products on the market. While CMS believes that existing codes, as indicated above, describe the products that are the subject of this request, as a general rule, CMS does not assign individual products to existing codes on behalf of any insurer. Individual insurers have the necessary flexibility to assign individual products to existing codes in the manner consistent with their individual policies and programmatic needs. For coding guidance, please refer to the insurer(s) in whose jurisdiction(s) claim would be filed. For Medicaid, contact the Medicaid Agency in the state in which the claims would be filed. For private insurance, contact the individual private insurance entity. Under contract to CMS, the Pricing, Data Analysis and Coding (PDAC) provides coding verifications for the purpose of billing Medicare. For confirmation of appropriate code assignment for Medicare billing, you may contact the PDAC Contact Center toll free at 877-735-1326. For your convenience, the PDAC has compiled a product classification system called DMECS that lists individual products by brand name under code categories. This system is available at: http://www.dmepdac.com. If you do not find your product listed by the PDAC matrix, you may request a coding verification for your product by contacting the PDAC at the toll free telephone number listed above.	Existing code S5561, "Insulin delivery device, reusable pen; 3 ml size", or A4211, "Supplies for self-administered injections" are available for assignments by insurers to describe the pen and/or dosage calculator application, if they deem appropriate. The Level II HCPCS codes describe categories of similar items. The code set is not intended to be an exhaustive listing of all products on the market. While CMS believes that existing codes, as indicated above, describe the products that are the subject of this request, as a general rule, CMS does not assign individual products to existing codes on behalf of any insurer. Individual insurers have the necessary flexibility to assign individual products to existing codes in the manner consistent with their individual policies and programmatic needs. For coding guidance, please refer to the insurer(s) in whose jurisdiction(s) claim would be filed. For Medicaid, contact the Medicaid Agency in the state in which the claims would be filed. For private insurance, contact the individual private insurance entity. Under contract to CMS, the Pricing, Data Analysis and Coding (PDAC) provides coding verifications for the purpose of billing Medicare. For confirmation of appropriate code assignment for Medicare billing, you may contact the PDAC Contact Center toll free at 877-735-1326. For your convenience, the PDAC has compiled a product classification system called DMECS that lists individual products by brand name under code categories. This system is available at: http://www.dmepdac.com. If you do not find your product listed by the PDAC matrix, you may request a coding verification for your product by contacting the PDAC at the toll free telephone number listed above.
19.127	Request to establish a new Level II HCPCS code to identify a molded thermoplastic barrier for use by persons who self-propel a manual wheelchair to prevent hand contact with the wheels, Trade Name: The Shield.	The Shield wheelchair barrier is not primarily medical in nature, and therefore not suitable for inclusion in the Level II HCPCS.	CMS did not identify policy or claims processing need on the part of any insurance sector to establish a code to identify the shield. Add stock language to "refer to insurers for coding guidance."
19.128	Request to establish a new Level II HCPCS code to identify tandem t:slim X2 insulin pump. Applicant's suggested language: EXXXX "External ambulatory insulin infusion pump and therapeutic CGM receiver.	Establish new code EXXXX "External ambulatory infusion pump, insulin, dosage rate adjustment using therapeutic continuous glucose sensing" Establish new code AXXXX "Supplies for maintenance of insulin infusion pump with dosage rate adjustment using therapeutic continuous glucose sensing, per week"	Establish a new Level II HCPCS code E0787 "External ambulatory infusion pump, insulin, dosage rate adjustment using therapeutic continuous glucose sensing", Establish a new Level II HCPCS code A4226 "Supplies for maintenance of insulin infusion pump with dosage rate adjustment using therapeutic continuous glucose sensing, per week". Effective 1/1/2020.

19.129	Request to establish a new Level II HCPCS code to identify a rechargeable electric wearable breast pump that fits in a bra, Trade Name: Willow Wearable Breast Pump. Applicant's suggested language: E060X "Breast pump, battery-powered, wearable entirely inside bra."	Existing code category E0603 "Breast pump, electric (ac and/or dc), any type" adequately describes the Willow Breast Pump and is available for assignment by insurers if they deem appropriate. The Level II HCPCS codes describe categories of similar items. The code set is not intended to be an exhaustive listing of all products on the market. While CMS believes that existing code, as indicated above, describes the product that is the subject of this request, as a general rule, CMS does not assign individual products to existing codes on behalf of any insurer. Individual insurers have the necessary flexibility to assign individual products to existing codes in the manner consistent with their individual policies and programmatic needs. For coding guidance, please refer to the insurer(s) in whose jurisdiction(s) claim would be filed. For Medicare, contact the Medicare contractor. For Medicaid, contact the Medicaid Agency in the state in which the claim would be filed. For private insurance, contact the individual private insurance entity.	Existing code category E0603 "Breast pump, electric (ac and/or dc), any type" adequately describes the Willow Breast Pump and is available for assignment by insurers if they deem appropriate. The Level II HCPCS codes describe categories of similar items. The code set is not intended to be an exhaustive listing of all products on the market. While CMS believes that existing code, as indicated above, describes the product that is the subject of this request, as a general rule, CMS does not assign individual products to existing codes on behalf of any insurer. Individual insurers have the necessary flexibility to assign individual products to existing codes in the manner consistent with their individual policies and programmatic needs. For coding guidance, please refer to the insurer(s) in whose jurisdiction(s) claim would be filed. For Medicare, contact the Medicare contractor. For Medicaid, contact the Medicaid Agency in the state in which the claim would be filed. For private insurance, contact the individual private insurance entity.
19.130	Request to establish a new Level II HCPCS code to identify a hand-held foam roller manual "traction" or massage device, Trade Name: Tiger Tail. Applicant's suggested language: EXXXX "Tiger Tail."	The Tiger Tail device is not primarily medical in nature, and as such, not suitable for coding in Level II HCPCS.	CMS upheld its preliminary decision and modified decision language for clarity. CMS did not identify policy and claims processing need to establish unique code to identify the Tiger Tail. Add stock language to "refer to insurers for coding guidance"
19.131	Request to establish a new Level II HCPCS code to identify walk-in Portable Hydrotherapy tubs, Trade Name: Portable Hydrotherapy Units.	Portable hydrotherapy tubs are not primarily medical in nature and as such, are not suitable for coding in Level II HCPCS.	Establish a new Level II HCPCS code K1003 "Whirlpool tub, walk-in, portable". Effective 01/01/2020
19.133	Series of three separate applications to establish three new Level II HCPCS codes to identify Surgilube, based on packaging and amount provided per package. Applicant's suggested language: 1. "Sterile Surgical Lubricant, Per Ounce," to identify sterile surgical Lubricant provided in tubes; 2. "Sterile Surgical Lubricant, per packet," to describe 3g and 5g foilpacs; and 3. "Sterile Surgical Lubricant PER ounce specialty packaging," to describe 31 gm foilpacs and 5 gm metal tubes.	Existing codes A4402 "Lubricant, per ounce"; A4332 "Lubricant, individual sterile packet, each"; and A4559 "Coupling gel or paste, for use with ultrasound device, per ounce", adequately describe the lubricants that are the subject of these requests and are available for assignment by insurers if they deem appropriate to describe Surgilube depending on the product characteristics and the amount supplied. The applicant's claim of a therapeutic distinction between pap test results using carbomer vs: non-carbomer lubricant is not substantiated in the information provided by the applicant. And pricing is not a coding criteria. The Level II HCPCS codes describe categories of similar items. The code set is not intended to be an exhaustive listing of all products on the market. While CMS believes that existing codes, as indicated above, describe the products that are the subject of this request, as a general rule, CMS does not assign individual products to existing codes on behalf of any insurer. Individual insurers have the necessary flexibility to assign individual products to existing codes in the manner consistent with their individual policies and programmatic needs. For coding guidance, please refer to the insurer(s) in whose jurisdiction(s) claim would be filed. For Medicaid, contact the Medicaid Agency in the state in which the claims would be filed. For private insurance, contact the individual private insurance entity. Under contract to CMS, the Pricing, Data Analysis and Coding (PDAC) provides coding verifications for the purpose of billing Medicare. For confirmation of appropriate code assignment for Medicare billing, you may contact the PDAC Contact Center toll free at 877-735-1326. For your convenience, the PDAC has compiled a product classification system called DMECS that lists individual products by brand name under code categories. This system is available at: http://www.dmepdac.com. If you do not find your product listed by the PDAC matrix, you may request a coding verification for your product by contacting the PDAC at the toll free telephone number listed above.	Existing codes A4402 "Lubricant, per ounce"; A4332 "Lubricant, individual sterile packet, each"; and A4559 "Coupling gel or paste, for use with ultrasound device, per ounce", adequately describe the lubricants that are the subject of these requests and are available for assignment by insurers if they deem appropriate to describe Surgilube depending on the product characteristics and the amount supplied. The applicant's claim of a therapeutic distinction between pap test results using carbomer vs: non-carbomer lubricant is not substantiated in the information provided by the applicant. And pricing is not a coding criteria. The Level II HCPCS codes describe categories of similar items. The code set is not intended to be an exhaustive listing of all products on the market. While CMS believes that existing codes, as indicated above, describe the products that are the subject of this request, as a general rule, CMS does not assign individual products to existing codes on behalf of any insurer. Individual insurers have the necessary flexibility to assign individual products to existing codes in the manner consistent with their individual policies and programmatic needs. For coding guidance, please refer to the insurer(s) in whose jurisdiction(s) claim would be filed. For Medicaid, contact the Medicaid Agency in the state in which the claims would be filed. For private insurance, contact the individual private insurance entity. Under contract to CMS, the Pricing, Data Analysis and Coding (PDAC) provides coding verifications for the purpose of billing Medicare. For confirmation of appropriate code assignment for Medicare billing, you may contact the PDAC Contact Center toll free at 877-735-1326. For your convenience, the PDAC has compiled a product classification system called DMECS that lists individual products by brand name under code categories. This system is available at: http://www.dmepdac.com. If you do not find your product listed by the PDAC matrix, you may request a coding verification for your product by contacting the PDAC at the toll free telephone number listed above.
19.134	Series of three separate applications to establish three new Level II HCPCS codes to identify Surgilube, based on packaging and amount provided per package. Applicant's suggested language: 1. "Sterile Surgical Lubricant, Per Ounce," to identify sterile surgical Lubricant provided in tubes; 2. "Sterile Surgical Lubricant, per packet," to describe 3g and 5g foilpacs; and 3. "Sterile Surgical Lubricant PER ounce specialty packaging," to describe 31 gm foilpacs and 5 gm metal tubes.	Existing codes A4402 "Lubricant, per ounce"; A4332 "Lubricant, individual sterile packet, each"; and A4559 "Coupling gel or paste, for use with ultrasound device, per ounce", adequately describe the lubricants that are the subject of these requests and are available for assignment by insurers if they deem appropriate to describe Surgilube depending on the product characteristics and the amount supplied. The applicant's claim of a therapeutic distinction between pap test results using carbomer vs: non-carbomer lubricant is not substantiated in the information provided by the applicant. And pricing is not a coding criteria. The Level II HCPCS codes describe categories of similar items. The code set is not intended to be an exhaustive listing of all products on the market. While CMS believes that existing codes, as indicated above, describe the products that are the subject of this request, as a general rule, CMS does not assign individual products to existing codes on behalf of any insurer. Individual insurers have the necessary flexibility to assign individual products to existing codes in the manner consistent with their individual policies and programmatic needs. For coding guidance, please refer to the insurer(s) in whose jurisdiction(s) claim would be filed. For Medicaid, contact the Medicaid Agency in the state in which the claims would be filed. For private insurance, contact the individual private insurance entity. Under contract to CMS, the Pricing, Data Analysis and Coding (PDAC) provides coding verifications for the purpose of billing Medicare. For confirmation of appropriate code assignment for Medicare billing, you may contact the PDAC Contact Center toll free at 877-735-1326. For your convenience, the PDAC has compiled a product classification system called DMECS that lists individual products by brand name under code categories. This system is available at: http://www.dmepdac.com. If you do not find your product listed by the PDAC matrix, you may request a coding verification for your product by contacting the PDAC at the toll free telephone number listed above.	Existing codes A4402 "Lubricant, per ounce"; A4332 "Lubricant, individual sterile packet, each"; and A4559 "Coupling gel or paste, for use with ultrasound device, per ounce", adequately describe the lubricants that are the subject of these requests and are available for assignment by insurers if they deem appropriate to describe Surgilube depending on the product characteristics and the amount supplied. The applicant's claim of a therapeutic distinction between pap test results using carbomer vs: non-carbomer lubricant is not substantiated in the information provided by the applicant. And pricing is not a coding criteria. The Level II HCPCS codes describe categories of similar items. The code set is not intended to be an exhaustive listing of all products on the market. While CMS believes that existing codes, as indicated above, describe the products that are the subject of this request, as a general rule, CMS does not assign individual products to existing codes on behalf of any insurer. Individual insurers have the necessary flexibility to assign individual products to existing codes in the manner consistent with their individual policies and programmatic needs. For coding guidance, please refer to the insurer(s) in whose jurisdiction(s) claim would be filed. For Medicaid, contact the Medicaid Agency in the state in which the claims would be filed. For private insurance, contact the individual private insurance entity. Under contract to CMS, the Pricing, Data Analysis and Coding (PDAC) provides coding verifications for the purpose of billing Medicare. For confirmation of appropriate code assignment for Medicare billing, you may contact the PDAC Contact Center toll free at 877-735-1326. For your convenience, the PDAC has compiled a product classification system called DMECS that lists individual products by brand name under code categories. This system is available at: http://www.dmepdac.com. If you do not find your product listed by the PDAC matrix, you may request a coding verification for your product by contacting the PDAC at the toll free telephone number listed above.

		telephone number listed above.	
19.135	Series of three separate applications to establish three new Level II HCPCS codes to identify Surgilube, based on packaging and amount provided per package.

Applicant's suggested language:

1. "Sterile Surgical Lubricant, Per Ounce," to identify sterile surgical Lubricant provided in tubes;

2. "Sterile Surgical Lubricant, per packet," to describe 3g and 5g foilpacs; and

3. "Sterile Surgical Lubricant PER ounce specialty packaging," to describe 31 gm foilpacs and 5 gm metal tubes. | Existing codes A4402 "Lubricant, per ounce"; A4332 "Lubricant, individual sterile packet, each"; and A4559 "Coupling gel or paste, for use with ultrasound device, per ounce", adequately describe the lubricants that are the subject of these requests and are available for assignment by insurers if they deem appropriate to describe Surgilube depending on the product characteristics and the amount supplied. The applicant's claim of a therapeutic distinction between pap test results using carbomer vs: non-carbomer lubricant is not substantiated in the information provided by the applicant. And pricing is not a coding criteria.

The Level II HCPCS codes describe categories of similar items. The code set is not intended to be an exhaustive listing of all products on the market. While CMS believes that existing codes, as indicated above, describe the products that are the subject of this request, as a general rule, CMS does not assign individual products to existing codes on behalf of any insurer. Individual insurers have the necessary flexibility to assign individual products to existing codes in the manner consistent with their individual policies and programmatic needs. For coding guidance, please refer to the insurer(s) in whose jurisdiction(s) claim would be filed. For Medicaid, contact the Medicaid Agency in the state in which the claims would be filed. For private insurance, contact the individual private insurance entity.

Under contract to CMS, the Pricing, Data Analysis and Coding (PDAC) provides coding verifications for the purpose of billing Medicare. For confirmation of appropriate code assignment for Medicare billing, you may contact the PDAC Contact Center toll free at 877-735-1326. For your convenience, the PDAC has compiled a product classification system called DMECS that lists individual products by brand name under code categories. This system is available at: http://www.dmepdac.com. If you do not find your product listed by the PDAC matrix, you may request a coding verification for your product by contacting the PDAC at the toll free telephone number listed above. | Existing codes A4402 "Lubricant, per ounce"; A4332 "Lubricant, individual sterile packet, each"; and A4559 "Coupling gel or paste, for use with ultrasound device, per ounce", adequately describe the lubricants that are the subject of these requests and are available for assignment by insurers if they deem appropriate to describe Surgilube depending on the product characteristics and the amount supplied. The applicant's claim of a therapeutic distinction between pap test results using carbomer vs: non-carbomer lubricant is not substantiated in the information provided by the applicant. And pricing is not a coding criteria.

The Level II HCPCS codes describe categories of similar items. The code set is not intended to be an exhaustive listing of all products on the market. While CMS believes that existing codes, as indicated above, describe the products that are the subject of this request, as a general rule, CMS does not assign individual products to existing codes on behalf of any insurer. Individual insurers have the necessary flexibility to assign individual products to existing codes in the manner consistent with their individual policies and programmatic needs. For coding guidance, please refer to the insurer(s) in whose jurisdiction(s) claim would be filed. For Medicaid, contact the Medicaid Agency in the state in which the claims would be filed. For private insurance, contact the individual private insurance entity.

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| 19.136 | Request to establish a new Level II HCPCS code to identify disposable milk bags for use with the Willow Wearable Breast Pump.

Applicant's suggested language: AXXXX "Milk collection and storage bag, single-use (per box of 24)." | Establish AXXXX " Disposable collection and storage bag for breast milk, any size, any type, each". | Establish new Level II HCPCS code K1005 "Disposable collection and storage bag for breast milk, any size, any type, each".

Effective 01/01/2020 |
| 19.137 | Request to make newly established code A4563 (Effective 1/1/2019), which identifies a rectal control system for vaginal insertion, an "L" code (using the identical language), for the purpose "allowing providers to bill a separately payable L-code for the Eclipse System along with the E/M code that must be used for the second clinician visit." | HCPCS code alpha characters do not confer benefit category or reimbursement status on the part of any insurer, and alpha character designations for HCPCS codes are determined by CMS separate and apart from our external code application procedures. However; CMS reviewed the concerns expressed by this applicant, and it is our understanding that the OPPS status indicator for code A4563 has been revised, enabling separate Medicare payment when appropriate. We believe this action resolves the applicants stated concerns. | HCPCS code alpha characters are not dispositive of benefit category or reimbursement status of the product, on the part of any insurer; are not an indicator of relative complexity of the product. Alpha character designations for HCPCS codes are determined by CMS separate and apart from our external code application procedures. However; CMS reviewed the concerns expressed by this applicant, and it is our understanding that the OPPS status indicator for code A4563 has been revised, enabling separate Medicare payment when appropriate. We believe this action resolves the applicants stated concerns. |
| 19.138 | Request to establish a new Level II HCPCS code to identify the "Lumbrella" Lumbar Sacral Orthosis (LSO). | Existing Level II HCPCS code category L0650 "Lumbar-sacral orthosis, sagittal-coronal control, with rigid anterior and posterior frame/panel(s), posterior extends from sacrococcygeal junction to t-9 vertebra, lateral strength provided by rigid lateral frame/panel(s), produces intracavitary pressure to reduce load on intervertebral discs, includes straps, closures, may include padding, shoulder straps, pendulous abdomen design, prefabricated, off-the-shelf " adequately describes the Lumbrella LSO and its functionality.

The Level II HCPCS codes describe categories of similar items. The code set is not intended to be an exhaustive listing of all products on the market. While CMS believes that an existing code, as indicated above, describes the product that is the subject of this request, as a general rule, CMS does not assign individual products to existing codes on behalf of any insurer. Individual insurers have the necessary flexibility to assign individual products to existing codes in the manner consistent with their individual policies and programmatic needs. For coding guidance, please refer to the insurer(s) in whose jurisdiction(s) claim would be filed. For Medicaid, contact the Medicaid Agency in the state in which the claims would be filed. For private insurance, contact the individual private insurance entity.

Under contract to CMS, the Pricing, Data Analysis and Coding (PDAC) provides coding verifications for the purpose of billing Medicare. For confirmation of appropriate code assignment for Medicare billing, you may contact the PDAC Contact Center toll free at 877-735-1326. For your convenience, the PDAC has compiled a product classification system called DMECS that lists individual products by brand name under code categories. This system is available at: http://www.dmepdac.com. If you do not find your product listed by the PDAC matrix, you may request a coding verification for your product by contacting the PDAC at the toll free telephone number listed above. | Existing Level II HCPCS code category L0650 "Lumbar-sacral orthosis, sagittal-coronal control, with rigid anterior and posterior frame/panel(s), posterior extends from sacrococcygeal junction to t-9 vertebra, lateral strength provided by rigid lateral frame/panel(s), produces intracavitary pressure to reduce load on intervertebral discs, includes straps, closures, may include padding, shoulder straps, pendulous abdomen design, prefabricated, off-the-shelf ", addresses intracavitary pressure and adequately describes the Lumbrella LSO and its functionality.

The Level II HCPCS codes describe categories of similar items. The code set is not intended to be an exhaustive listing of all products on the market. While CMS believes that an existing code, as indicated above, describes the product that is the subject of this request, as a general rule, CMS does not assign individual products to existing codes on behalf of any insurer. Individual insurers have the necessary flexibility to assign individual products to existing codes in the manner consistent with their individual policies and programmatic needs. For coding guidance, please refer to the insurer(s) in whose jurisdiction(s) claim would be filed. For Medicaid, contact the Medicaid Agency in the state in which the claims would be filed. For private insurance, contact the individual private insurance entity.

Under contract to CMS, the Pricing, Data Analysis and Coding (PDAC) provides coding verifications for the purpose of billing Medicare. For confirmation of appropriate code assignment for Medicare billing, you may contact the PDAC Contact Center toll free at 877-735-1326. For your convenience, the PDAC has compiled a product classification system called DMECS that lists individual products by brand name under code categories. This system is available at: http://www.dmepdac.com. If you do not find your product listed by the PDAC matrix, you may request a coding verification for your product by contacting the PDAC at the toll free telephone number listed above. |
| 19.139 | Request to establish a new Level II HCPCS code to identify C-Brace Microprocessor Stance and Swing phase Knee-Ankle-Foot-Orthosis, Trade Name: C-Brace.

Applicant's suggested language: L2XXX "Microprocessor controlled knee-ankle-foot-orthosis." | The CMS needs additional time to fully consider this request. We would appreciate input from the applicant and others pertaining to the following questions:

Does the C-Brace, in any way, assist in movement or have an active drive function?

What is the average length of time the device is used by a typical patient?

Is the microprocessor control (powered unit) feature necessary for the bracing function?

How is this feature necessary for the Effective use of the brace in restricting or eliminating motion in a diseased or injured leg? | Establish a new Level II HCPCS code L2006 "Knee ankle foot device, any material, single or double upright, swing and/or stance phase microprocessor control with adjustability, includes all components (e.g., sensors, batteries, charger), any type activation, with or without ankle joint(s), custom fabricated". Effective 1/1/2020 |

		Is the device attached to the leg capable of functioning as a brace in the absence of input from the powered unit? If the powered device fails to function, what is its default state? What muscle and muscle function does the powered unit replace?	
19.140	Request to establish two new Level II HCPCS codes to identify BrainPort Vision Pro and training services. Applicants suggested language: LXXX1 "Vision aid prosthetic system, including intro-oral simulation device, headset with integrated digital video camera, and patient controls" LXXX2 "Vision aid prosthetic system, training services, and individual, up to 10 hours."	CMS is not aware of a claims processing need on the part of any insurance sector to establish code to report the BrainPort Vision Pro adjunctive device to other assistive methods. CMS refers the applicant to the American Medical Association (AMA) for coding guidance for reporting individual training services.	CMS is not aware of a claims processing need on the part of any insurance sector to establish code to report the BrainPort Vision Pro adjunctive device to other assistive methods. CMS refers the applicant to the American Medical Association (AMA) for coding guidance for reporting individual training services.
19.141	Request to 1) revise existing Level II HCPCS code L8032 which currently reads "Nipple prosthesis, reusable, any type, each" to instead read "Areola/Nipple prosthesis, retail/Mass produced, 3 month reusable, each"; and 2) establish a new Level II HCPCS code to identify a nipple prosthesis service. Applicant's suggested language: L80XX "Areola/Nipple Prosthesis, service/individually produced, 2 year reusable, each."	Establish new code LXXXX "nipple prosthesis, custom fabricated, reusable, any material, any type, each." Revise existing code L8032, which currently reads: "nipple prosthesis, reusable, any type, each", to instead read: "nipple prosthesis, prefabricated, reuseable, any type, each".	1) Establish a new Level II HCPCS code L8033 "nipple prosthesis, custom fabricated, reusable, any material, any type, each." 2) Revise existing code L8032, which currently reads: "nipple prosthesis, reusable, any type, each", to instead read: "nipple prosthesis, prefabricated, reusable, any type, each". The service component is included in the custom code, as with any custom prosthesis. Effective. 1/1/2020
19.142	Request to establish a new Level II HCPCS code to identify a remote dosage controller for use by patients in conjunction with a surgically implanted carbon dioxide (CO2) gas-controlled tissue expander. Trade name: AirXpanders AeroForm Dosage Controller. Applicant's suggested language: LXXXX Remote dosage controller, (external) for use with implantable tissue expander in breast reconstruction following mastectomy.	The tissue expander is inserted during a post mastectomy reconstructive surgery in the hospital inpatient setting. The external remote controller for use by the patient with the implanted tissue expander is provided on an initial issue prior to patient discharge from the hospital and as such, is included in the hospital payment and not suitable for coding in HCPCS Level II. Separate reporting of this external component could be considered redundant.	The tissue expander is inserted during a post mastectomy reconstructive surgery in the hospital inpatient setting. The external remote controller for use by the patient with the implanted tissue expander is opened, paired and tested with the specific AirXpander in the operating room during the surgical procedure and as such, is included in the hospital payment and not suitable for coding in HCPCS Level II. Separate reporting of this external component could be considered redundant.
19.143	Request to modify an existing Level II HCPCS code A9277 which currently reads, "Transmitter, external, for use with interstitial continuous glucose monitoring system" to instead read, "Transmitter; external, for use with interstitial continuous glucose monitoring system, 1 unit = 1 day supply."	This request to revise the descriptor of existing code A9277 has not been approved. The requested change to add a billing unit does not improve the code.	This request to revise the descriptor of existing code A9277 has not been approved. The requested change to add a billing unit does not improve the code. For billing guidance, contact the insurer in whose jurisdiction the claim would be filed.
19.145	Repeat request to remove wound dressings from existing all-inclusive code E0446 "Topical Oxygen delivery system, not otherwise specified, includes all supplies and accessories". This request to establish a series of four new Level II HCPCS codes to separately identify composite dressings for use with topical oxygen delivery system for continuous diffusion of oxygen. Trade names: OxySpur and OxySpur Lite Oxygen Diffusion Dressings. Applicant's suggested language: Xxxx1 High exudate composite dressing, sterile, pad size 16 sq. in. or less, with integrated oxygen diffusion cannula, with or without adhesive border, for use with topical oxygen delivery system for continuous diffusion of oxygen system Xxxx2 High exudate composite dressing, sterile, pad size more than 16 sq. in. but less than 48 sq. in., with integrated oxygen diffusion cannula, with or without adhesive border, for use with topical oxygen delivery system for continuous diffusion of oxygen system Xxxx3 Low exudate composite dressing, sterile, pad size 16 sq. in. or less, with integrated oxygen diffusion cannula, with or without adhesive border, for use with topical oxygen delivery system for continuous diffusion of oxygen system Xxxx4 Low exudate composite dressing, sterile, pad size more than 16 sq. in. but less than 48 sq. in., with integrated oxygen diffusion cannula, with or without adhesive border, for use with topical oxygen delivery system for continuous diffusion of oxygen system	Existing code E0446 "Topical Oxygen delivery system, not otherwise specified, includes all supplies and accessories", and is intended to be all inclusive. As such, separate reporting of dressings might be considered redundant.	Existing code E0446 "Topical Oxygen delivery system, not otherwise specified, includes all supplies and accessories", and is intended to be all inclusive. As such, separate reporting of dressings might be considered redundant. The HCPCS Level II codes describe categories of like items. The code set is not intended to be an exhaustive listing of all products on the market. While CMS believes that existing code E0446 describes this product, as a general rule, the CMS does not classify individual items into code categories on behalf of insurers. Individual insurers have the necessary flexibility to classify specific products into HCPCS Level II code categories and establish their own coding instructions in accordance with their policies and program operating needs. Questions regarding classification of products into HCPCS Level II code categories should be submitted to the insurer in whose jurisdiction a claim would be filed. For private sector health insurance systems, please contact the individual private insurance entity. For Medicaid systems, please contact the Medicaid Agency in the state in which the claim is being filed.

19.146	Repeat request to establish another Level II HCPCS code to identify a wearable continuous diffusion of oxygen (CDO) therapy device, Trade Name: TransCu O2 Oxygen Generator; and to specify within the code that the payment methodology is "rental". Applicant's suggested language: E044X "Topical oxygen delivery system for continuous diffusion of oxygen, rental; includes portable continuous oxygen concentrator, rechargeable batteries, charging system and carrying case";	Existing code E0446 "Topical oxygen delivery system, not otherwise specified, includes all supplies and accessories", and is intended to be all-inclusive. As the applicant acknowledges, the TransCu O2 is, in fact, the predicate product for the original establishment of this code. The HCPCS Level II codes describe categories of like items. The code set is not intended to be an exhaustive listing of all products on the market. While CMS believes that existing code E0446 describes this product, as a general rule, the CMS does not classify individual items into code categories on behalf of insurers. Individual insurers have the necessary flexibility to classify specific products into HCPCS Level II code categories and establish their own coding instructions in accordance with their policies and program operating needs. Questions regarding classification of products into HCPCS Level II code categories should be submitted to the insurer in whose jurisdiction a claim would be filed. For private sector health insurance systems, please contact the individual private insurance entity. For Medicaid systems, please contact the Medicaid Agency in the state in which the claim is being filed.	Existing code E0446 "Topical oxygen delivery system, not otherwise specified, includes all supplies and accessories", and is intended to be all-inclusive. As the applicant acknowledges, the TransCu O2 is, in fact, the predicate product for the original establishment of this code. The HCPCS Level II codes describe categories of like items. The code set is not intended to be an exhaustive listing of all products on the market. While CMS believes that existing code E0446 describes this product, as a general rule, the CMS does not classify individual items into code categories on behalf of insurers. Individual insurers have the necessary flexibility to classify specific products into HCPCS Level II code categories and establish their own coding instructions in accordance with their policies and program operating needs. Questions regarding classification of products into HCPCS Level II code categories should be submitted to the insurer in whose jurisdiction a claim would be filed. For private sector health insurance systems, please contact the individual private insurance entity. For Medicaid systems, please contact the Medicaid Agency in the state in which the claim is being filed.
19.147	Request to establish a new Level II HCPCS code to identify a service/fee for dispensing prescription medications (excluding inhalation drugs and compounding of medications). Applicant's suggested language: Prescription drug(s) dispensing service/fee	This request to establish a new code to separately identify a dispensing fee for prescription drugs (excluding inhalation drugs and compounding of medicine), has not been approved. Pharmacy dispensing fees relate to pricing and payments are not, of themselves medical products. Existing dispensing fee codes for inhalation drugs are included on an exception basis and are associated with statutory requirements in 1842(o) of the SSA. Insurers are paying dispensing fees without difficulty, and the addition of a code could create duplicate billing opportunities or "inflated" drug cost, due to provider-added charges, as reported by the applicant. For coding and billing guidance and information regarding allowable fees, contact the insurer in whose jurisdiction a claim would be filed.	This request to establish a new code to separately identify a dispensing fee for prescription drugs (excluding inhalation drugs and compounding of medicine), has not been approved. CMS did not identify claims processing need on the part of any insurer. Existing dispensing fee codes for inhalation drugs are included on an exception basis and are associated with statutory requirements in 1842(o) of the SSA. CMS carefully considered this matter and determined that insurers, including medicaid state agencies, are paying dispensing fees without difficulty, and the addition of a code could create duplicate billing opportunities or "inflated" drug cost, due to provider-added charges, as reported by the applicant. For coding and billing guidance and information regarding allowable fees, contact the insurer in whose jurisdiction a claim would be filed.
19.148	Request to establish a "not otherwise classified" Level II HCPCS code for blood products.	Establish new code PXXXX "Blood component or product not otherwise classified"	Establish new Level II HCPCS code P9099 "Blood component or product not otherwise classified". Effective 1/1/2020
19.149	Request to revise 46 existing Level II HCPCS procedure codes. Applicant's suggested language: add the phrase "via in-person or via telemedicine" to each of the 46 existing Level II HCPCS procedure codes listed below.	CMS would like to thank the applicant; the LAPPL; its membership; and all first responders, for their commitment and service in protecting American Citizens. We appreciate your interest in and Effectiveorts in improving health care, and access to care, and in engaging CMS via your applications and additional, follow up communications with CMS staff. Regarding identification of location of service, we would like to call your attention to a place of service (POS) code #02, newly published in 2017, "Telehealth": "The location where health services and health related services are provided or received, through a telecommunication system". Place of service codes are for use by health care providers on professional claims to specify the entity where service(s) were rendered. The entire POS code set can be found at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/Downloads/Website-POS-database.pdf. For payment and policy information pertaining to the telehealth POS code, we refer the applicant to the insurers in whose jurisdictions claims would be filed. For example: the individual private insurance entity, the Medicaid Agency in the state in which a claim would filed, the Medicare contractor, VA or DOD.	Regarding identification of location of service, we believe that the use of currently available, national Place Of Service (POS) codes developed by CMS and available for assignment by any insurer to identify and report site of service on claims forms submitted to insurers, communicate the information necessary for insurers to identify and adjudicate claims for telehealth and alternative sites of service, in accordance with their individual policies and programs. Place of service codes are reported by health care providers, together with service and procedure codes, on professional claims to specify the entity where service(s) were rendered. In particular, we would like to call your attention to a place of service (POS) code #02, newly published in 2017, "Telehealth": "The location where health services and health related services are provided or received, through a telecommunication system". We would also like to call to your attention two other POS codes that might be particularly useful in reporting care to first responders as you described to CMS: POS code # 11 "Office", "Location, other than a hospital, skilled nursing facility (SNF), military treatment facility, community health center, State or local public health clinic, or intermediate care facility (ICF), where the health professional routinely provides health examinations, diagnosis, and treatment of illness or injury on an ambulatory basis; and POS code #12 "Home", " Location, other than a hospital or other facility, where the patient receives care in a private residence. The entire POS code set can be found at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/Downloads/Website-POS-database.pdf. For payment and policy information and coding guidance pertaining to the telehealth and/or use of POS codes, we refer you to the insurers in whose jurisdictions claims would be filed. For example: the individual private insurance entity, the Medicaid Agency in the state in which a claim would filed, the Medicare contractor, VA or DOD.
19.150	Request to establish a new level II HCPCS code to identify trastuzumab-qyyp, Trade Name: Trazimera. Applicant's suggested language: QXXXX "Injection, trastuzumab-qyyp, biosimilar, (Trazimera), 10 mg"		Establish Q5116 "Injection, trastuzumab-qyyp, biosimilar, (Trazimera), 10 mg
19.151	Request to establish a new Level II HCPCS code to identify Trastuzumab-anns, Trade Name: Kanjinti. Applicant's suggested language: "Injection, trastuzumab-anns, biosimilar, (Kanjinti), 10 mg".		Establish Q5117 "Injection, trastuzumab-anns, biosimilar, (Kanjinti), 10 mg". Effective 10/1/19.
19.152	Request to establish a new Level II HCPCS code to identify bevacizumab-bvzr, Trade Name: Zirabev. Applicant's suggested language: "Injection, bevacizumab-bvzr, biosimilar, (Zirabev), 10 mg".		Establish Q5118 "Injection, bevacizumab-bvzr, biosimilar, (Zirabev), 10 mg". Effective 10/1/19.
19.153	Request to establish a new Level II HCPCS code to identify Polatuzumab vedotin-piiq, Trade Name: Polivy. Applicant's suggested language: "Injection, polatuzumab vedotin-piiq, 10mg".		Establish a new Level II HCPCS code J9309 "Injection, polatuzumab vedotin-piiq, 1 mg," Effective. 01/01/2020

| 19.154 | Request to establish a new Level II HCPCS code to identify brolucizumab-dbll, Trade name: Beovu. Applicant suggested language: "Injection, Brolucizumab-dbll, 6 mg." | | Establish a new Level II HCPCS code J0179 "Injection, brolucizumab-dbll, 1 mg." Effective. 01/01/2020 |