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Annual ICD-10 and Quarterly CPT/HCPCS Code Updates

The following Medical Policies, Medical Benefit Drug Policies, Coverage Determination Guidelines, and Utilization Review Guidelines have been updated to reflect the annual ICD-10 and quarterly CPT/HCPCS code additions, revisions, and deletions. Refer to the following sources for information on the code updates:

- American Medical Association: Current Procedural Terminology: CPT®
- Centers for Medicare & Medicaid Services (CMS): International Classification of Diseases, Tenth Revision (ICD-10) Clinical Modification (CM) (Diagnosis) Codes: 2022
- Centers for Medicare & Medicaid Services (CMS): International Classification of Diseases, Tenth Revision (ICD-10) Procedure Coding System (PCS) Codes: 2022
- Centers for Medicare & Medicaid Services (CMS): Healthcare Common Procedure Coding System (HCPCS) Quarterly Update

Policy Title	Effective Date	Policy Type	Summary of Changes
Airway Clearance Devices	Oct. 1, 2022	Medical Policy	• Revised description for HCPCS code E0483
Cell-Free Fetal DNA Testing	Oct. 1, 2022	Medical Policy	• Added ICD-10 diagnosis codes O35.00X0, O35.01X0, O35.02X0, O35.03X0, O35.04X0, O35.05X0, O35.06X0, O35.07X0, O35.08X0, O35.09X0, O35.10X0, O35.11X0, O35.12X0, O35.13X0, O35.14X0, O35.15X0, O35.19X0, O35.AXX0, O35.BXX0, O35.CXX0, O35.DXX0, O35.EXX0, O35.FXX0, O35.GXX0, and O35.HXX0 • Removed ICD-10 diagnosis codes O35.0XX0 and O35.1XX0
Chromosome Microarray Testing (Non-Oncology Conditions)	Dec. 1, 2022	Medical Policy	• Added ICD-10 diagnosis codes O35.00X0, O35.00X1, O35.00X2, O35.00X3, O35.00X4, O35.00X5, O35.00X9, O35.01X0, O35.01X1, O35.01X2, O35.01X3, O35.01X4, O35.01X5, O35.01X9, O35.02X0, O35.02X1, O35.02X2, O35.02X3, O35.02X4, O35.02X5, O35.02X9, O35.03X0, O35.03X1, O35.03X2, O35.03X3, O35.03X4, O35.03X5, O35.03X9, O35.04X0, O35.04X1, O35.04X2, O35.04X3, O35.04X4, O35.04X5, O35.04X9, O35.05X0, O35.05X1, O35.05X2, O35.05X3, O35.05X4, O35.05X5, O35.05X9, O35.06X0, O35.06X1, O35.06X2, O35.06X3, O35.06X4, O35.06X5, O35.06X9, O35.07X0, O35.07X1, O35.07X2, O35.07X3, O35.07X4, O35.07X5, O35.07X9, O35.08X0, O35.08X1, O35.08X2, O35.08X3, O35.08X4, O35.08X5, O35.08X9, O35.09X0, O35.09X1, O35.09X2, O35.09X3, O35.09X4, O35.09X5, O35.09X9, O35.10X0, O35.10X1, O35.10X2, O35.10X3, O35.10X4, O35.10X5, O35.10X9, O35.11X0, O35.11X1, O35.11X2, O35.11X3, O35.11X4, O35.11X5, O35.11X9, O35.12X0, O35.12X1, O35.12X2, O35.12X3, O35.12X4, O35.12X5, O35.12X9, O35.13X0, O35.13X1, O35.13X2, O35.13X3, O35.13X4, O35.13X5, O35.13X9, O35.14X0, O35.14X1, O35.14X2, O35.14X3, O35.14X4, O35.14X5, O35.14X9, O35.15X0,

Policy Title	Effective Date	Policy Type	Summary of Changes
Chromosome Microarray Testing (Non-Oncology Conditions) (continued)	Dec. 1, 2022	Medical Policy	O35.15X1, O35.15X2, O35.15X3, O35.15X4, O35.15X5, O35.15X9, O35.19X0, O35.19X1, O35.19X2, O35.19X3, O35.19X4, O35.19X5, O35.19X9, O35.AXX0, O35.AXX1, O35.AXX2, O35.AXX3, O35.AXX4, O35.AXX5, O35.AXX9, O35.BXX0, O35.BXX1, O35.BXX2, O35.BXX3, O35.BXX4, O35.BXX5, O35.BXX9, O35.CXX0, O35.CXX1, O35.CXX2, O35.CXX3, O35.CXX4, O35.CXX5, O35.CXX9, O35.DXX0, O35.DXX1, O35.DXX2, O35.DXX3, O35.DXX4, O35.DXX5, O35.DXX9, O35.EXX0, O35.EXX1, O35.EXX2, O35.EXX3, O35.EXX4, O35.EXX5, O35.EXX9, O35.FXX0, O35.FXX1, O35.FXX2, O35.FXX3, O35.FXX4, O35.FXX5, O35.FXX9, O35.GXX0, O35.GXX1, O35.GXX2, O35.GXX3, O35.GXX4, O35.GXX5, O35.GXX9, O35.HXX0, O35.HXX1, O35.HXX2, O35.HXX3, O35.HXX4, O35.HXX5, O35.HXX9, Q21.10, Q21.11, Q21.12, Q21.13, Q21.14, Q21.15, Q21.16, Q21.19, Q21.20, Q21.21, Q21.22, and Q21.23 • Removed ICD-10 diagnosis codes O35.0XX0, O35.0XX1, O35.0XX2, O35.0XX3, O35.0XX4, O35.0XX5, O35.0XX9, O35.1XX0, O35.1XX1, O35.1XX2, O35.1XX3, O35.1XX4, O35.1XX5, O35.1XX9, Q21.1, and Q21.2
Clotting Factors, Coagulant Blood Products & Other Hemostatics	Oct. 1, 2022	Medical Benefit Drug Policy	• Added ICD-10 diagnosis codes D68.00, D68.01, D68.020, D68.021, D68.022, D68.023, D68.029, D68.03, D68.04, and D68.09 • Removed ICD-10 diagnosis code D68.0
Complement Inhibitors (Soliris® & Ultomiris®)	Oct. 1, 2022	Medical Benefit Drug Policy	• Added ICD-10 diagnosis codes D59.30, D59.32, and D59.39 • Removed ICD-10 diagnosis code D59.3
Enjaymo™ (Sutimlimab-Jome)	Oct. 1, 2022	Medical Benefit Drug Policy	• Replaced HCPCS codes J3490 and J3590 with J1302 • Removed HCPCS code C9094
Epidural Steroid Injections for Spinal Pain	Nov. 1, 2022	Medical Policy	• Added ICD-10 diagnosis codes M51.A0, M51.A1, M51.A2, M51.A3, M51.A4, and M51.A5
Genitourinary Pathogen Nucleic Acid Detection Panel Testing	Oct. 1, 2022	Medical Policy	• Added CPT code 0352U
Gonadotropin Releasing Hormone Analogs	Oct. 1, 2022	Medical Benefit Drug Policy	• Added ICD-10 diagnosis codes N80.00, N80.01, N80.02, N80.03, N80.101, N80.102, N80.103, N80.109, N80.111, N80.112, N80.113, N80.119, N80.121, N80.122, N80.123, N80.129, N80.201, N80.202, N80.203, N80.209, N80.211, N80.212, N80.213, N80.219, N80.221, N80.222, N80.223, N80.229, N80.30, N80.311, N80.312, N80.319, N80.321, N80.322, N80.329, N80.331, N80.332, N80.333, N80.339, N80.341, N80.342,

Policy Title	Effective Date	Policy Type	Summary of Changes
Gonadotropin Releasing Hormone Analogs (continued)	Oct. 1, 2022	Medical Benefit Drug Policy	N80.343, N80.349, N80.351, N80.352, N80.353, N80.359, N80.361, N80.362, N80.363, N80.369, N80.371, N80.372, N80.373, N80.379, N80.381, N80.382, N80.383, N80.389, N80.391, N80.392, N80.399, N80.3A1, N80.3A2, N80.3A3, N80.3A9, N80.3B1, N80.3B2, N80.3B3, N80.3B9, N80.3C1, N80.3C2, N80.3C3, N80.3C9, N80.40, N80.41, N80.42, N80.50, N80.511, N80.512, , 80.519, N80.521, N80.522, N80.529, N80.531, N80.532, N80.539, N80.541, N80.542, N80.549, N80.551, N80.552, N80.559, N80.561, N80.562, N80.569, N80.A0, N80.A1, N80.A2, N80.A41, N80.A42, N80.A43, N80.A49, N80.A51, N80.A52, N80.A53, N80.A59, N80.A61, N80.A62, N80.A63, N80.A69, N80.B1, N80.B2, N80.B31, N80.B32, N80.B39, N80.B4, N80.B5, N80.B6, N80.C0, N80.C10, N80.C11, N80.C19, N80.C2, N80.C3, N80.C4, N80.C9, N80.D0, N80.D1, N80.D2, N80.D3, N80.D4, N80.D5, N80.D6, and N80.D9 • Removed ICD-10 diagnosis codes N80.0, N80.1, N80.2, N80.3, and N80.4
Hepatitis Screening	Dec. 1, 2022	Medical Policy	• Added ICD-10 diagnosis codes D68.00, D68.01, D68.020, D68.021, D68.022, D68.023, D68.029, D68.03, D68.04, D68.09, F11.91, F13.91, F14.91, F15.91, F16.91, F18.91, F19.91, K76.82, O35.00X0, O35.00X1, O35.00X2, O35.00X3, O35.00X4, O35.00X5, O35.00X9, O35.01X0, O35.01X1, O35.01X2, O35.01X3, O35.01X4, O35.01X5, O35.01X9, O35.02X0, O35.02X1, O35.02X2, O35.02X3, O35.02X4, O35.02X5, O35.02X9, O35.03X0, O35.03X1, O35.03X2, O35.03X3, O35.03X4, O35.03X5, O35.03X9, O35.04X0, O35.04X1, O35.04X2, O35.04X3, O35.04X4, O35.04X5, O35.04X9, O35.05X0, O35.05X1, O35.05X2, O35.05X3, O35.05X4, O35.05X5, O35.05X9, O35.06X0, O35.06X1, O35.06X2, O35.06X3, O35.06X4, O35.06X5, O35.06X9, O35.07X0, O35.07X1, O35.07X2, O35.07X3, O35.07X4, O35.07X5, O35.07X9, O35.08X0, O35.08X1, O35.08X2, O35.08X3, O35.08X4, O35.08X5, O35.08X9, O35.09X0, O35.09X1, O35.09X2, O35.09X3, O35.09X4, O35.09X5, O35.09X9, O35.10X0, O35.10X1, O35.10X2, O35.10X3, O35.10X4, O35.10X5, O35.10X9, O35.11X0, O35.11X1, O35.11X2, O35.11X3, O35.11X4, O35.11X5, O35.11X9, O35.12X0, O35.12X1, O35.12X2, O35.12X3, O35.12X4, O35.12X5, O35.12X9, O35.13X0, O35.13X1, O35.13X2, O35.13X3, O35.13X4, O35.13X5, O35.13X9, O35.14X0, O35.14X1, O35.14X2, O35.14X3, O35.14X4, O35.14X5, O35.14X9, O35.15X0, O35.15X1, O35.15X2, O35.15X3, O35.15X4,

Policy Title	Effective Date	Policy Type	Summary of Changes
Hepatitis Screening (continued)	Dec. 1, 2022	Medical Policy	O35.15X5, O35.15X9, O35.19X0, O35.19X1, O35.19X2, O35.19X3, O35.19X4, O35.19X5, O35.19X9, O35.AXX0, O35.AXX1, O35.AXX2, O35.AXX3, O35.AXX4, O35.AXX5, O35.AXX9, O35.BXX0, O35.BXX1, O35.BXX2, O35.BXX3, O35.BXX4, O35.BXX5, O35.BXX9, O35.CXX0, O35.CXX1, O35.CXX2, O35.CXX3, O35.CXX4, O35.CXX5, O35.CXX9, O35.DXX0, O35.DXX1, O35.DXX2, O35.DXX3, O35.DXX4, O35.DXX5, O35.DXX9, O35.EXX0, O35.EXX1, O35.EXX2, O35.EXX3, O35.EXX4, O35.EXX5, O35.EXX9, O35.FXX0, O35.FXX1, O35.FXX2, O35.FXX3, O35.FXX4, O35.FXX5, O35.FXX9, O35.GXX0, O35.GXX1, O35.GXX2, O35.GXX3, O35.GXX4, O35.GXX5, O35.GXX9, O35.HXX0, O35.HXX1, O35.HXX2, O35.HXX3, O35.HXX4, O35.HXX5, and O35.HXX9 • Removed ICD-10 diagnosis codes D68.0, O35.0XX0, O35.0XX1, O35.0XX2, O35.0XX3, O35.0XX4, O35.0XX5, O35.0XX9, O35.1XX0, O35.1XX1, O35.1XX2, O35.1XX3, O35.1XX4, O35.1XX5, and O35.1XX9
Immune Globulin (IVIG and SCIG)	Oct. 1, 2022	Medical Benefit Drug Policy	• Added ICD-10 diagnosis code D81.82
Light and Laser Therapy	Oct. 1, 2022	Medical Policy	• Added ICD-10 diagnosis codes Q85.81, Q85.82, Q85.83, and Q85.89 • Removed ICD-10 diagnosis code Q85.8
Molecular Oncology Testing for Cancer Diagnosis, Prognosis, and Treatment Decisions	Oct. 1, 2022	Medical Policy	• Added CPT codes 0332U, 0333U, 0334U, 0339U, 0340U, and 0343U • Removed CPT codes 0013U, 0014U, and 0056U
Obstetrical Ultrasound	Oct. 1, 2022	Medical Policy	• Added ICD-10 diagnosis codes O35.00X0, O35.00X1, O35.00X2, O35.00X3, O35.00X4, O35.00X5, O35.00X9, O35.01X0, O35.01X1, O35.01X2, O35.01X3, O35.01X4, O35.01X5, O35.01X9, O35.02X0, O35.02X1, O35.02X2, O35.02X3, O35.02X4, O35.02X5, O35.02X9, O35.03X0, O35.03X1, O35.03X2, O35.03X3, O35.03X4, O35.03X5, O35.03X9, O35.04X0, O35.04X1, O35.04X2, O35.04X3, O35.04X4, O35.04X5, O35.04X9, O35.05X0, O35.05X1, O35.05X2, O35.05X3, O35.05X4, O35.05X5, O35.05X9, O35.06X0, O35.06X1, O35.06X2, O35.06X3, O35.06X4, O35.06X5, O35.06X9, O35.07X0, O35.07X1, O35.07X2, O35.07X3, O35.07X4, O35.07X5, O35.07X9, O35.08X0, O35.08X1, O35.08X2, O35.08X3, O35.08X4, O35.08X5, O35.08X9, O35.09X0, O35.09X1, O35.09X2, O35.09X3, O35.09X4, O35.09X5, O35.09X9, O35.10X0, O35.10X1, O35.10X2, O35.10X3, O35.10X4, O35.10X5,

Policy Title	Effective Date	Policy Type	Summary of Changes
Obstetrical Ultrasound (continued)	Oct. 1, 2022	Medical Policy	O35.10X9, O35.11X0, O35.11X1, O35.11X2, O35.11X3, O35.11X4, O35.11X5, O35.11X9, O35.12X0, O35.12X1, O35.12X2, O35.12X3, O35.12X4, O35.12X5, O35.12X9, O35.13X0, O35.13X1, O35.13X2, O35.13X3, O35.13X4, O35.13X5, O35.13X9, O35.14X0, O35.14X1, O35.14X2, O35.14X3, O35.14X4, O35.14X5, O35.14X9, O35.15X0, O35.15X1, O35.15X2, O35.15X3, O35.15X4, O35.15X5, O35.15X9, O35.19X0, O35.19X1, O35.19X2, O35.19X3, O35.19X4, O35.19X5, O35.19X9, O35.AXX0, O35.AXX1, O35.AXX2, O35.AXX3, O35.AXX4, O35.AXX5, O35.AXX9, O35.BXX0, O35.BXX1, O35.BXX2, O35.BXX3, O35.BXX4, O35.BXX5, O35.BXX9, O35.CXX0, O35.CXX1, O35.CXX2, O35.CXX3, O35.CXX4, O35.CXX5, O35.CXX9, O35.DXX0, O35.DXX1, O35.DXX2, O35.DXX3, O35.DXX4, O35.DXX5, O35.DXX9, O35.EXX0, O35.EXX1, O35.EXX2, O35.EXX3, O35.EXX4, O35.EXX5, O35.EXX9, O35.FXX0, O35.FXX1, O35.FXX2, O35.FXX3, O35.FXX4, O35.FXX5, O35.FXX9, O35.GXX0, O35.GXX1, O35.GXX2, O35.GXX3, O35.GXX4, O35.GXX5, O35.GXX9, O35.HXX0, O35.HXX1, O35.HXX2, O35.HXX3,O35.HXX4, O35.HXX5, and O35.HXX9 • Removed ICD-10 diagnosis codes O35.0XX1, O35.0XX2, O35.0XX3, O35.0XX4, O35.0XX5, O35.0XX9, O35.1XX0, O35.1XX1, O35.1XX2, O35.1XX3, O35.1XX4, O35.1XX5, and O35.1XX9
Omnibus Codes	Oct. 1, 2022	Medical Policy	External Upper Limb Tremor Stimulators of the Peripheral Nerves of the Wrist • Revised description for HCPCS code K1019
Oncology Medication Clinical Coverage	Oct. 1, 2022	Medical Benefit Drug Policy	• Added HCPCS code C9142
Ophthalmologic Policy: Vascular Endothelial Growth Factor (VEGF) Inhibitors	Oct. 1, 2022	Medical Benefit Drug Policy	• Replaced HCPCS codes J3490 and J3590 with J2777 • Removed HCPCS code C9097
Pharmacogenetic Testing	Oct. 1, 2022	Medical Policy	• Added CPT codes 0345U, 0347U, 0348U, 0349U, and 0350U
Preventive Care Services	Oct. 1, 2022	Coverage Determination Guideline	Atherosclerosis • Added ICD-10 diagnosis codes I25.112, I25.702, I25.712, I25.722, I25.732, I25.752, I25.762, and I25.792 Pregnancy

Policy Title	Effective Date	Policy Type	Summary of Changes
Preventive Care Services (continued)	Oct. 1, 2022	Coverage Determination Guideline	• Added ICD-10 diagnosis codes O35.00X0, O35.00X1, O35.00X2, O35.00X3, O35.00X4, O35.00X5, O35.00X9, O35.01X0, O35.01X1, O35.01X2, O35.01X3, O35.01X4, O35.01X5, O35.01X9, O35.02X0, O35.02X1, O35.02X2, O35.02X3, O35.02X4, O35.02X5, O35.02X9, O35.03X0, O35.03X1, O35.03X2, O35.03X3, O35.03X4, O35.03X5, O35.03X9, O35.04X0, O35.04X1, O35.04X2, O35.04X3, O35.04X4, O35.04X5, O35.04X9, O35.05X0, O35.05X1, O35.05X2, O35.05X3, O35.05X4, O35.05X5, O35.05X9, O35.06X0, O35.06X1, O35.06X2, O35.06X3, O35.06X4, O35.06X5, O35.06X9, O35.07X0, O35.07X1, O35.07X2, O35.07X3, O35.07X4, O35.07X5, O35.07X9, O35.08X0, O35.08X1, O35.08X2, O35.08X3, O35.08X4, O35.08X5, O35.08X9, O35.09X0, O35.09X1, O35.09X2, O35.09X3, O35.09X4, O35.09X5, O35.09X9, O35.10X0, O35.10X1, O35.10X2, O35.10X3, O35.10X4, O35.10X5, O35.10X9, O35.11X0, O35.11X1, O35.11X2, O35.11X3, O35.11X4, O35.11X5, O35.11X9, O35.12X0, O35.12X1, O35.12X2, O35.12X3, O35.12X4, O35.12X5, O35.12X9, O35.13X0, O35.13X1, O35.13X2, O35.13X3, O35.13X4, O35.13X5, O35.13X9, O35.14X0, O35.14X1, O35.14X2, O35.14X3, O35.14X4, O35.14X5, O35.14X9, O35.15X0, O35.15X1, O35.15X2, O35.15X3, O35.15X4, O35.15X5, O35.15X9, O35.19X0, O35.19X1, O35.19X2, O35.19X3, O35.19X4, O35.19X5, O35.19X9, O35.AXX0, O35.AXX1, O35.AXX2, O35.AXX3, O35.AXX4, O35.AXX5, O35.AXX9, O35.BXX0, O35.BXX1, O35.BXX2, O35.BXX3, O35.BXX4, O35.BXX5, O35.BXX9, O35.CXX0, O35.CXX1, O35.CXX2, O35.CXX3, O35.CXX4, O35.CXX5, O35.CXX9, O35.DXX0, O35.DXX1, O35.DXX2, O35.DXX3, O35.DXX4, O35.DXX5, O35.DXX9, O35.EXX0, O35.EXX1, O35.EXX2, O35.EXX3, O35.EXX4, O35.EXX5, O35.EXX9, O35.FXX0, O35.FXX1, O35.FXX2, O35.FXX3, O35.FXX4, O35.FXX5, O35.FXX9, O35.GXX0, O35.GXX1, O35.GXX2, O35.GXX3, O35.GXX4, O35.GXX5, O35.GXX9, O35.HXX0, O35.HXX1, O35.HXX2, O35.HXX3, O35.HXX4, O35.HXX5, and O35.HXX9 • Removed ICD-10 diagnosis codes O35.0XX0, O35.0XX1, O35.0XX2, O35.0XX3, O35.0XX4, O35.0XX5, O35.0XX9, O35.1XX0, O35.1XX1, O35.1XX2, O35.1XX3, O35.1XX4, O35.1XX5, and O35.1XX9
Provider Administered Drugs – Site of Care	Oct. 1, 2022	Utilization Review Guideline	• Added HCPCS code J1302 • Removed HCPCS code C9094

Take Note

Policy Title	Effective Date	Policy Type	Summary of Changes
Synagis® (Palivizumab)	Oct. 1, 2022	Medical Benefit Drug Policy	• Added ICD-10 diagnosis codes D81.82, Q21.10, Q21.11, Q21.12, Q21.13, Q21.14, Q21.15, Q21.16, Q21.19, Q21.20, Q21.21, Q21.22, and Q21.23 • Removed ICD-10 diagnosis codes Q21.1 and Q21.2
Vitamin D Testing	Oct. 1, 2022	Medical Policy	• Added ICD-10 diagnosis codes Z79.60, Z79.61, Z79.620, Z79.621, Z79.622, Z79.623, Z79.624, Z79.630, Z79.631, Z79.632, Z79.633, Z79.634, Z79.64, Z79.69, and Z79.85 • Revised description for ICD-10 diagnosis codes C84.40, C84.41, C84.42, C84.43, C84.44, C84.45, C84.46, C84.47, C84.48, and C84.49
White Blood Cell Colony Stimulating Factors	Oct. 1, 2022	Medical Benefit Drug Policy	• Replaced HCPCS codes J3490 and J3590 with Q5125 • Removed HCPCS code C9096
Whole Exome and Whole Genome Sequencing	Oct. 1, 2022	Medical Policy	• Added CPT codes 0335U and 0336U • Removed CPT codes 0012U, 0013U, and 0014U

New

Policy Title	Effective Date	Coverage Rationale

Surgical Treatment of Lymphedema	Dec. 1, 2022	Surgical procedures for the treatment or prevention of Lymphedema are unproven and not medically necessary due to insufficient evidence of safety and/or efficacy. These procedures include, but are not limited to:
		• Liposuction/Lipectomy
		• Microsurgical treatment
		  ○ Lymphaticovenous anastomosis
		  ○ Lymphovenous bypass
		• Vascularized Lymph Node Transfer

Updated

Policy Title	Effective Date	Summary of Changes

Autologous Cellular Therapy	Dec. 1, 2022	**Definitions**
		• Updated definition of:
		  ○ Autologous Cellular Therapy
		  ○ Autologous Adipose-Derived Regenerative Cellular Therapy
		Supporting Information
		• Updated *Description of Services*, *Clinical Evidence,* and *References* sections to reflect the most current information

Breast Imaging for Screening and Diagnosing Cancer	Dec. 1, 2022	**Definitions** • Updated definition of "Automated Breast Ultrasound (ABUS)" **Supporting Information** • Updated *Clinical Evidence*, *FDA*, and *References* sections to reflect the most current information

Cell-Free Fetal DNA Testing	Oct. 1, 2022	**Documentation Requirements**
		• Updated list of CPT codes with associated documentation requirements; 0327U
		Applicable Codes
		• Updated list of ICD-10 diagnosis codes to reflect annual edits:
		  ○ Added O35.00X0, O35.01X0, O35.02X0, O35.03X0, O35.04X0, O35.05X0, O35.06X0, O35.07X0, O35.08X0, O35.09X0, O35.10X0, O35.11X0, O35.12X0, O35.13X0, O35.14X0, O35.15X0, O35.19X0, O35.AXX0, O35.BXX0, O35.CXX0, O35.DXX0, O35.EXX0, O35.FXX0, O35.GXX0, and O35.HXX0
		  ○ Removed O35.0XX0 and O35.1XX0

Sacroiliac Joint Interventions	Dec. 1, 2022	**Definitions**
		• Updated definition of:
		  ○ Titanium Triangular Implant
		  ○ Sacroiliac Joint
		• Removed definition of:

Updated

Policy Title	Effective Date	Summary of Changes
Sacroiliac Joint Interventions (continued)	Dec. 1, 2022	○ Arthrodesis ○ Axial Skeleton ○ Minimally Invasive Procedure ○ Percutaneous ○ Provocative Tests ○ Sacroiliac Joint Fusion ○ Sacroiliac Joint Pain **Supporting Information** ● Updated *Clinical Evidence*, *FDA*, and *References* sections to reflect the most current information

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Balloon Sinus Ostial Dilation	Nov. 1, 2022	**Coverage Rationale** ● Revised coverage criteria: *Chronic Rhinosinusitis* ○ Replaced criterion requiring: ▪ "Persistence of symptoms despite administration of full courses of antibiotic therapy, if bacterial infection is suspected; intranasal corticosteroids; and nasal lavage" with "persistence of symptoms despite *medical management with* administration of full courses of antibiotic therapy, if bacterial infection is suspected; intranasal corticosteroids *(and/or oral corticosteroids when*	Balloon sinus ostial dilation is proven and medically necessary for either of the following conditions: ● Chronic Rhinosinusitis which has all of the following: ○ Lasted longer than 12 weeks ○ Persistence of symptoms despite medical management with administration of full courses of all of the following treatments: ▪ Intranasal corticosteroids (and/or oral corticosteroids when appropriate); and ▪ Antibiotic therapy if bacterial infection is suspected; and ▪ Nasal lavage/irrigation if appropriate ○ Confirmation of Chronic Rhinosinusitis on a Recent Computed Tomography (CT) Scan for each sinus to be dilated meeting all of the following criteria: ▪ CT images are obtained after completion of medical management; and ▪ Documentation of which sinus has the disease and the extent of disease including the percent of opacification or the use of a scale such as the Modified Lund-Mackay Scoring System; and ▪ CT findings include one or more of the following: – Bony remodeling – Bony thickening – Opacified sinus

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Balloon Sinus Ostial Dilation (continued)	Nov. 1, 2022	*appropriate)*; and nasal lavage/*irrigation if appropriate*" ▪ "Confirmation of Chronic Rhinosinusitis on a computed tomography (CT) scan for each sinus to be dilated meeting all of the [listed] criteria" with "confirmation of Chronic Rhinosinusitis on a *Recent* Computed Tomography (CT) Scan for each sinus to be dilated meeting all of the [listed] criteria" *Recurrent Acute Rhinosinusitis* ○ Replaced criterion requiring "CT scan evidence of ostial obstruction (outflow tract obstruction) and mucosal thickening in the sinus to be dilated" with "*Recent* CT Scan evidence of ostial obstruction (outflow tract obstruction) and mucosal thickening in the sinus to be dilated" Documentation Requirements ● Updated list of *Required Clinical Information* to reflect/include: ○ Diagnosis ○ History of illness ○ Recent physical exam ○ Signs and symptoms	– Ostial obstruction (outflow tract obstruction) and mucosal thickening ○ Sinonasal symptoms such as pain, pressure, or drainage are present on the same side as CT scan findings of rhinosinusitis ○ The balloon sinus ostial dilation limited to the frontal, maxillary, or sphenoid sinuses ○ The balloon sinus ostial dilation performed as either a stand-alone procedure or part of Functional Endoscopic Sinus Surgery (FESS) ● Recurrent Acute Rhinosinusitis with all of the following: ○ Four or more episodes per year with distinct symptom free intervals between episodes; and ○ Recent Computed Tomography (CT) Scan evidence of ostial obstruction (outflow tract obstruction) and mucosal thickening in the sinus to be dilated; and ○ Sinonasal symptoms such as pain, pressure, or drainage are present on the same side as CT scan findings of rhinosinusitis Balloon sinus ostial dilation is unproven and not medically necessary for treating the following due to insufficient evidence of efficacy: ● Nasal polyps or tumors ● All other conditions that do not meet the above criteria Self-expanding absorptive sinus ostial dilation is unproven and not medically necessary for evaluating or treating sinusitis and all other conditions due to insufficient evidence of efficacy.

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Balloon Sinus Ostial Dilation (continued)	Nov. 1, 2022	○ Treatments tried, failed, or contraindicated; include the dates and reason for discontinuation (e.g. intranasal corticosteroids, antibiotic therapy, nasal lavage/irrigation) ○ Recent CT Scan report including the date of scan, documenting the following: ▪ Which sinus has the disease, including side ▪ The extent of disease including the percent of opacification or the use of a scale such as the Modified Lund-Mackay Scoring System ▪ Whether the images were taken pre- or post-medical management ○ Upon request, Recent CT Scan images: ▪ That show the abnormality for which surgery is being requested ▪ Are the optimal images to show the abnormality of the affected area including, when applicable the use of a scale such as the Modified Lund-Mackay Scoring System to define	

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Balloon Sinus Ostial Dilation (continued)	Nov. 1, 2022	severity ▪ Labeled with the date taken and the applicable case number obtained at time of notification, or member's name and ID number ▪ Note: CT images can be submitted via the external portal at uhcprovider.com/paan; faxes will not be accepted ○ For Chronic Rhinosinusitis also including the following: ▪ Evidence that the sinusitis involves frontal, maxillary, or sphenoid sinuses ▪ Planned procedure, including if the procedure will be part of a functional endoscopic sinus surgery (FESS) ○ For Recurrent Acute Rhinosinusitis also include the number of episodes per year of Acute Rhinosinusitis **Definitions** ● Added definition of "Recent Computed Tomography (CT) Scan" **Supporting Information** ● Updated *Clinical Evidence* and *References* sections to reflect the most current information	

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**

Epidural Steroid Injections for Spinal Pain	Nov. 1, 2022	Coverage Rationale
		• Revised coverage criteria:
		  ○ Added criterion requiring:
		  ▪ Evidence of nerve impingement by imaging or EMG
		  ▪ The injection is performed under fluoroscopic or CT guidance
		  ▪ There is no evidence of a condition that would contraindicate Epidural Steroid Injections (ESIs); conditions that would contraindicate ESIs include but are not limited to:
		  – Spinal neoplasm
		  – Rapidly progressing neurological deficit
		  – Epidural abscess
		  – Infection at the site of injection
		  ○ Replaced criterion requiring:
		  ▪ "The injection is intended for the *short-term* management of *acute or subacute* radicular pain" with "the injection is intended for the management of Radicular Pain *as evidenced by history and physical exam*"
			Epidural Steroid Injections (ESI) are proven and medically necessary when all of the following criteria are met:
			• The injection is intended for the management of Radicular Pain as evidenced by history and physical exam; and
			• The Radicular Pain is unresponsive to conservative treatment for ≥ 4 weeks:
			  ○ Pharmacotherapy such as NSAIDS or acetaminophen; or
			  ○ Activity modification (including but not limited to heavy lifting, bending, spinal torsion activities); or
			  ○ PT or home exercise
			• Evidence of nerve impingement by imaging or EMG
			• The injection is performed under fluoroscopic or CT guidance
			• There is no evidence of a condition that would contraindicate ESIs. Conditions that would contraindicate ESIs include but are not limited to:
			  ○ Spinal neoplasm
			  ○ Rapidly progressing neurological deficit
			  ○ Epidural abscess
			  ○ Infection at the site of injection
			
			The following are unproven and not medically necessary due to insufficient evidence of efficacy:
			• The use of ultrasound guidance for ESIs
			• ESI for all other indications of the spine not included above
			
			Epidural Steroid Injection Limitations
			• A maximum of four (4) ESI sessions (per region, regardless of level, location, or side) per year
			  ○ A session is defined as one date of service in which ESI injection(s) are performed
			  ○ A region is defined by either the region of the cervical, thoracic or lumbosacral
			  ○ A year is defined as the 12-month period starting from the date of service of the first approved injection
			• Subsequent ESIs may be provided only if:

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Epidural Steroid Injections for Spinal Pain (continued)	Nov. 1, 2022	▪ "The radicular pain is unresponsive to pharmacotherapy such as NSAIDS or acetaminophen ≥ *3* weeks" with "the Radicular Pain is unresponsive to pharmacotherapy such as NSAIDS or acetaminophen ≥ *4* weeks" *Epidural Steroid Injection Limitations* • Changed frequency limitation from "a maximum of *three (3)* ESI sessions (per region, regardless of level, location, or side) per year" to "a maximum of *four (4)* ESI sessions (per region, regardless of level, location, or side) per year" Subsequent ESIs • Replaced reference to "*repeat* ESIs" with "*subsequent* ESIs" • Revised guidelines to indicate subsequent ESIs may be provided only if: ○ The pain has returned or deterioration in function has occurred; and ○ The previous injection resulted in ≥ 50% pain relief or functional improvement for three or more months as measured by validated	○ Pain has returned or deterioration in function has occurred; and ○ The previous injection resulted in ≥ 50% pain relief or functional improvement for three or more months as measured by validated measurement tools ; or ○ The previous injection resulted in ≤ 50% pain relief or functional improvement for less than three months as measured by validated measurement tools and there has been a reassessment of the individual and the injection site and technique

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Epidural Steroid Injections for Spinal Pain (continued)	Nov. 1, 2022	measurement tools; or ○ The previous injection resulted in ≤ 50% pain relief or functional improvement for less than three months as measured by validated measurement tools and there has been a reassessment of the individual and the injection site and technique **Documentation Requirements** ● Updated list of *Required Clinical Information*: *Initial Injection* ○ Removed: ▪ History of epidural injections in the previous 12 months, including location and clinical response to previous injections ○ Replaced: ▪ "Physical exam" with "physical exam *demonstrating presence of radicular pain*" ▪ "Relevant medical history" with "relevant medical history *related to the spine or surrounding tissues*" ▪ "Treatments tried, failed, or contraindicated; include the dates and reason for	

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Epidural Steroid Injections for Spinal Pain (continued)	Nov. 1, 2022	discontinuation" with "treatments tried *(e.g., pharmacotherapy, exercises)*, failed, or contraindicated; include the dates, *duration of treatment,* and reason for discontinuation" ▪ "Plan for use of ultrasound guidance" with "plan for use of *fluoroscopic, CT, or* ultrasound guidance" *Subsequent Injection* ○ Replaced: ▪ "Duration of the effect" with "*dates, location, and* duration of the effect *for the prior 12 months*" ▪ "Functional improvement as measured on a validated measurement tool, *such as the Oswestry Disability Index*" with "functional improvement as measured on a validated measurement tool" Definitions ● Added definition of: ○ Functional Impairments ● Removed definition of: ○ Acute Low Back Pain ○ Oswestry Disability Index (also	

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Epidural Steroid Injections for Spinal Pain (continued)	Nov. 1, 2022	known as the Oswestry Low Back Pain Disability Questionnaire) ○ Radiculopathy ○ Sub-Acute Low Back Pain **Applicable Codes** ● Updated list of ICD-10 diagnosis codes to reflect annual edits; added M51.A0, M51.A1, M51.A2, M51.A3, M51.A4, and M51.A5 **Supporting Information** ● Updated *References* section to reflect the most current information	
Facet Joint and Medial Branch Block Injections for Spinal Pain	Nov. 1, 2022	**Coverage Rationale** ● Revised language to indicate: ○ The following are proven and medically necessary: ▪ An initial diagnostic Facet Joint Injection/Medial Branch Block to determine facet joint origin when all of the following criteria are met: – Pain is exacerbated by facet loading maneuvers on physical examination (e.g., hyperextension, rotation) – Clinically significant improvement has not occurred (the pain remains at a 3 or more	The following are proven and medically necessary: ● An initial diagnostic Facet Joint Injection/Medial Branch Block to determine facet joint origin when all of the following criteria are met: ○ Pain is exacerbated by facet loading maneuvers on physical examination (e.g., hyperextension, rotation); and ○ Clinically significant improvement has not occurred (the pain remains at a 3 or more on a 1-10 pain scale) after a minimum of four weeks of conservative care (including but not limited to pharmacotherapy, exercise, or physical therapy); and ○ Clinical findings and imaging studies suggest no other cause of the pain (e.g., spinal stenosis with neurogenic claudication, disc herniation with radicular pain, infection, tumor, fracture, pain related to prior surgery); and ○ The spinal motion segment is not fused; and ○ A radiofrequency joint denervation/ablation procedure is being considered ● A second Facet Joint Injection/Medial Branch Block performed to confirm the validity of the clinical response to the initial Facet Joint Injection, when all of the following criteria are met: ○ Administered at the same level and side as the initial block; and

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Facet Joint and Medial Branch Block Injections for Spinal Pain (continued)	Nov. 1, 2022	on a 1-10 pain scale) after a minimum of four weeks of conservative care (including but not limited to pharmacotherapy, exercise, or physical therapy) – Clinical findings and imaging studies suggest no other cause of the pain (e.g., spinal stenosis with neurogenic claudication, disc herniation with radicular pain, infection, tumor, fracture, pain related to prior surgery) – The spinal motion segment is not fused – A radiofrequency joint denervation/ablation procedure is being considered ▪ A second Facet Joint Injection/Medial Branch Block performed to confirm the validity of the clinical response to the initial Facet Joint Injection,	○ The initial diagnostic Facet Joint Injection produced a positive response as demonstrated when all the following criteria are met: ▪ For at least the expected minimum duration of the effect of the local anesthetic; and ▪ Functional improvement that is specific to the individual with demonstrable improvement in the physical functions previously limited by the facetogenic pain and ○ A radiofrequency joint denervation/ablation procedure is being considered Facet Joint Injections/Medial Branch Blocks are unproven and not medically necessary due to insufficient evidence of efficacy: ● If radiofrequency ablation procedure not considered as treatment option at the requested level(s) ● For treating spinal pain, after diagnostic injections have been completed ● After two Facet Injections/Medial Branch Blocks at the same level and same side (this is considered therapeutic rather than diagnostic) ● Therapeutic Facet Joint Injections and/or Facet Nerve Block (i.e., Medial Branch Block) for treating chronic spinal pain ● For a second Facet Joint Injection/Medial Branch Block if the initial injection did not confirm the joint as the source of pain ● In the presence of untreated Radiculopathy at the same level as the intended diagnostic injection (with the exception of Radiculopathy caused by a facet joint synovial cyst) ● If injection of volume of local anesthetics exceeds 0.5ml for Medial Branch Blocks ● When performed under ultrasound guidance Therapeutic Facet Joint/Medial Branch Block Injections at the cervical, thoracic, and lumbar levels of the spine are unproven and not medically necessary due to insufficient evidence of efficacy and safety.

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Facet Joint and Medial Branch Block Injections for Spinal Pain (continued)	Nov. 1, 2022	when all of the following criteria are met: – Administered at the same level and side as the initial block – The initial diagnostic Facet Joint Injection produced a positive response as demonstrated when all the following criteria are met: • For at least the expected minimum duration of the effect of the local anesthetic • Functional improvement that is specific to the individual with demonstrable improvement in the physical functions previously limited by the facetogenic pain – A radiofrequency joint denervation/ablation procedure is being considered ○ Facet Joint Injections/Medial	

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Facet Joint and Medial Branch Block Injections for Spinal Pain (continued)	Nov. 1, 2022	Branch Blocks are unproven and not medically necessary due to insufficient evidence of efficacy: ▪ If radiofrequency ablation procedure not considered as treatment option at the requested level(s) ▪ For treating spinal pain, after diagnostic injections have been completed ▪ After two Facet Injections/Medial Branch Blocks at the same level and same side (this is considered therapeutic rather than diagnostic) ▪ Therapeutic Facet Joint Injections and/or Facet Nerve Block (i.e., Medial Branch Block) for treating chronic spinal pain ▪ For a second Facet Joint Injection/Medial Branch Block if the initial injection did not confirm the joint as the source of pain ▪ In the presence of untreated Radiculopathy at the same level as the intended diagnostic injection (with the exception of	

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Facet Joint and Medial Branch Block Injections for Spinal Pain (continued)	Nov. 1, 2022	Radiculopathy caused by a facet joint synovial cyst) ▪ If injection of volume of local anesthetics exceeds 0.5ml for Medial Branch Blocks ▪ When performed under ultrasound guidance ○ Therapeutic Facet Joint/Medial Branch Block Injections at the cervical, thoracic, and lumbar levels of the spine are unproven and not medically necessary due to insufficient evidence of efficacy and safety **Documentation Requirements** ● Updated list of *Required Clinical Information*: *Initial Injection* ○ Added: ▪ Severity of pain on a 1-10 scale after conservative treatment (e.g., pharmacotherapy, exercises) ○ Replaced: ▪ "Physical exam, including presence of *neurological deficits*" with "physical exam, including presence of *findings on facet loading maneuvers*" ▪ "Treatments tried, failed,	

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Facet Joint and Medial Branch Block Injections for Spinal Pain (continued)	Nov. 1, 2022	or contraindicated; include the dates and reason for discontinuation" with "treatments tried, failed, or contraindicated; include the dates, *duration of treatment*, and reason for discontinuation" ▪ "Plan for *neuroablation*" with "plan for *radiofrequency joint denervation/ablation procedure*" *Second Injection* ○ Removed "percentage of pain reduction" Supporting Information • Updated *Clinical Evidence* and *References* sections to reflect the most current information	
Functional Endoscopic Sinus Surgery (FESS)	Nov. 1, 2022	Coverage Rationale • Revised coverage criteria: *Chronic Rhinosinusitis* ○ Replaced criterion requiring: ▪ "Persistence of symptoms despite administration of full courses of all of the [listed] treatments" with "persistence of symptoms despite *medical management with* administration of full courses of all of the [listed]	Functional Endoscopic Sinus Surgery (FESS) is proven and medically necessary when one or more of the following conditions are present: • Chronic Rhinosinusitis (CRS) with or without polyps which has all of the following: ○ Lasted longer than 12 weeks ○ Persistence of symptoms despite medical management with administration of full courses of all of the following treatments: ▪ Intranasal corticosteroids (and/or oral corticosteroids when appropriate); and ▪ Antibiotic therapy if bacterial infection is suspected; and ▪ Nasal lavage/irrigation if appropriate ○ Confirmation of Chronic Rhinosinusitis on a Recent Computed Tomography (CT) Scan for each sinus to be treated meeting all of the

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Functional Endoscopic Sinus Surgery (FESS) (continued)	Nov. 1, 2022	treatments" ▪ "Confirmation of Chronic Rhinosinusitis on a computed tomography (CT) scan for each sinus to be dilated meeting all of the [listed] criteria" with "confirmation of Chronic Rhinosinusitis on a *Recent* Computed Tomography (CT) Scan for each sinus to be dilated meeting all of the [listed] criteria" *Recurrent Acute Rhinosinusitis* ○ Replaced criterion requiring "CT scan evidence of ostial obstruction (outflow tract obstruction) and mucosal thickening in the sinus to be dilated" with "*Recent* CT Scan evidence of ostial obstruction (outflow tract obstruction) and mucosal thickening in the sinus to be dilated" Documentation Requirements • Updated list of *Required Clinical Information* to reflect/include: ○ Diagnosis ○ History of illness ○ Recent physical exam ○ Signs and symptoms ○ Treatments tried, failed, or contraindicated; include the	following criteria: ▪ CT images are obtained after completion of medical management; and ▪ Documentation of which sinus has the disease and the extent of disease including the percent of opacification or the use of a scale such as the Modified Lund-Mackay Scoring System; and ▪ CT findings include one or more of the following: – Bony remodeling – Bony thickening – Opacified sinus – Ostial obstruction (outflow tract obstruction) and mucosal thickening ○ Sino nasal symptoms such as pain, pressure, or drainage are present on the same side as CT scan findings of rhinosinusitis • Recurrent Acute Rhinosinusitis (RARS) with all of the following: ○ Four or more episodes per year with distinct symptom free intervals between episodes; and ○ Sinonasal symptoms such as pain, pressure, or drainage are present on the same side as CT scan findings of rhinosinusitis; and ○ Recent Computed Tomography (CT) Scan evidence of one of the following: ▪ For the maxillary, frontal, or sphenoid sinuses, both of the following are present: – Ostial obstruction (outflow tract obstruction) in the sinus to be treated – Mucosal thickening in the sinus to be treated ▪ For the ethmoid sinus, mucosal thickening is present • Any of the following conditions confirmed on CT: ○ Complications of sinusitis such as abscess ○ Symptomatic concha bullosa ○ Symptomatic mucocele ○ Polyposis with obstructive symptoms (for Chronic Rhinosinusitis with polyps see the above criteria)

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Functional Endoscopic Sinus Surgery (FESS) (continued)	Nov. 1, 2022	dates and reason for discontinuation (e.g., intranasal corticosteroids, antibiotic therapy, nasal lavage/irrigation) ○ Recent CT Scan report, including the date of scan, documenting the following: ▪ Which sinus has the disease, including side ▪ The extent of disease including the percent of opacification or the use of a scale such as the Modified Lund-Mackay Scoring System ▪ Whether the images were taken pre- or post-medical management ○ Upon request, Recent CT Scan images: ▪ That show the abnormality for which surgery is being requested ▪ Are the optimal images to show the abnormality of the affected area including, when applicable the use of a scale such as the Modified Lund-Mackay Scoring System to define the severity ▪ Labeled with the date	○ Sinonasal tumor Functional Endoscopic Sinus Surgery (FESS) is unproven and not medically necessary for any condition other than those listed above due to insufficient evidence of efficacy.

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Functional Endoscopic Sinus Surgery (FESS) (continued)	Nov. 1, 2022	taken and the applicable case number obtained at time of notification, or member's name and ID number ▪ Note: CT images can be submitted via the external portal at uhcprovider.com/paan; faxes will not be accepted ○ For Recurrent Acute Rhinosinusitis, also include the number of episodes per year of Acute Rhinosinusitis **Definitions** • Added definition of: ○ Draf Classification System for Endoscopic Frontal Sinus Drainage ○ Recent Computed Tomography (CT) Scan **Supporting Information** • Updated *Clinical Evidence* and *References* sections to reflect the most current information	
Hepatitis Screening	Dec. 1, 2022	**Coverage Rationale** • Revised list of proven and medically necessary indications for Hepatitis B screening; replaced: ○ "Present sexual *partners of HCB-infected*" with "present sexual *partner is infected with HBV*"	Hepatitis A testing is proven and medically necessary for individuals who were born in or have travelled to regions with high or moderate prevalence of hepatitis A virus (HAV). Hepatitis B screening is proven and medically necessary in individuals with the following indications: • Blood transfusion prior to 1992 • Birth in or travel to regions with high or moderate prevalence of hepatitis B

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Hepatitis Screening (continued)	Dec. 1, 2022	○ "Current and past use of injection drug*; this includes those who injected once or a few times many years ago*" with "current and past *recreational* use of injection drug*(s), including those individuals with a history limited to a single use of injection drug and regardless of the duration since use*" **Definitions** • Updated definition of: ○ Hepatitis A Antibody Test ○ Hepatitis B Core Antibody Test ○ Hepatitis B Surface Antigen Test ○ Hepatitis C Antibody Test ○ Hepatitis E **Applicable Codes** • Updated list of ICD-10 diagnosis codes to reflect annual edits: ○ Added D68.00, D68.01, D68.020, D68.021, D68.022, D68.023, D68.029, D68.03, D68.04, D68.09, F11.91, F13.91, F14.91, F15.91, F16.91, F18.91, F19.91, K76.82, O35.00X0, O35.00X1, O35.00X2, O35.00X3, O35.00X4, O35.00X5, O35.00X9, O35.01X0, O35.01X1, O35.01X2,	virus (HBV) infection • Elevated ALT/AST of unknown etiology • Clotting-factor disorders, such as hemophilia • Exposure to blood or body fluids • Donors of blood, plasma, organs, tissue, or semen • Following exposure to an individual with HBV infection through household, secondary contacts or needle sharing • Hemodialysis • High-risk sexual behavior • HIV-positive infection, and those who are high risk of HIV acquisition • Immunosuppression due to immunosuppressive therapy for rheumatologic or gastroenterological disorders, chemotherapy, and organ transplantation • Infants born in the U.S. whose parents were born in regions with high rates of Hepatitis B • Infants born to HBV infected mothers • Men who have sexual relations with men (MSM) • Pregnancy • Present sexual partner is infected with HBV • Prior to anti-TNF initiation • Recipient of clotting factor concentrates made before 1987 • Recipients of blood or organs from a donor who later tested HBV positive • Residents and institutional care workers • Current and past recreational use of injection drug(s), including those individuals with a history limited to a single use of injection drug and regardless of the duration since use Hepatitis C virus (HCV) screening is proven and medically necessary in adults aged 18 to 79 years whether or not risk factors have been identified. Note: For additional information, refer to the Coverage Determination Guideline titled Preventive Care Services.

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Hepatitis Screening (continued)	Dec. 1, 2022	O35.01X3, O35.01X4, O35.01X5, O35.01X9, O35.02X0, O35.02X1, O35.02X2, O35.02X3, O35.02X4, O35.02X5, O35.02X9, O35.03X0, O35.03X1, O35.03X2, O35.03X3, O35.03X4, O35.03X5, O35.03X9, O35.04X0, O35.04X1, O35.04X2, O35.04X3, O35.04X4, O35.04X5, O35.04X9, O35.05X0, O35.05X1, O35.05X2, O35.05X3, O35.05X4, O35.05X5, O35.05X9, O35.06X0, O35.06X1, O35.06X2, O35.06X3, O35.06X4, O35.06X5, O35.06X9, O35.07X0, O35.07X1, O35.07X2, O35.07X3, O35.07X4, O35.07X5, O35.07X9, O35.08X0, O35.08X1, O35.08X2, O35.08X3, O35.08X4, O35.08X5, O35.08X9, O35.09X0, O35.09X1, O35.09X2, O35.09X3, O35.09X4, O35.09X5, O35.09X9, O35.10X0, O35.10X1, O35.10X2, O35.10X3, O35.10X4, O35.10X5,	

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Hepatitis Screening (continued)	Dec. 1, 2022	O35.10X9, O35.11X0, O35.11X1, O35.11X2, O35.11X3, O35.11X4, O35.11X5, O35.11X9, O35.12X0, O35.12X1, O35.12X2, O35.12X3, O35.12X4, O35.12X5, O35.12X9, O35.13X0, O35.13X1, O35.13X2, O35.13X3, O35.13X4, O35.13X5, O35.13X9, O35.14X0, O35.14X1, O35.14X2, O35.14X3, O35.14X4, O35.14X5, O35.14X9, O35.15X0, O35.15X1, O35.15X2, O35.15X3, O35.15X4, O35.15X5, O35.15X9, O35.19X0, O35.19X1, O35.19X2, O35.19X3, O35.19X4, O35.19X5, O35.19X9, O35.AXX0, O35.AXX1, O35.AXX2, O35.AXX3, O35.AXX4, O35.AXX5, O35.AXX9, O35.BXX0, O35.BXX1, O35.BXX2, O35.BXX3, O35.BXX4, O35.BXX5, O35.BXX9, O35.CXX0, O35.CXX1, O35.CXX2, O35.CXX3, O35.CXX4, O35.CXX5, O35.CXX9, O35.DXX0, O35.DXX1,	

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Hepatitis Screening (continued)	Dec. 1, 2022	O35.DXX2, O35.DXX3, O35.DXX4, O35.DXX5, O35.DXX9, O35.EXX0, O35.EXX1, O35.EXX2, O35.EXX3, O35.EXX4, O35.EXX5, O35.EXX9, O35.FXX0, O35.FXX1, O35.FXX2, O35.FXX3, O35.FXX4, O35.FXX5, O35.FXX9, O35.GXX0, O35.GXX1, O35.GXX2, O35.GXX3, O35.GXX4, O35.GXX5, O35.GXX9, O35.HXX0, O35.HXX1, O35.HXX2, O35.HXX3, O35.HXX4, O35.HXX5, and O35.HXX9 ○ Removed D68.0, O35.0XX0, O35.0XX1, O35.0XX2, O35.0XX3, O35.0XX4, O35.0XX5, O35.0XX9, O35.1XX0, O35.1XX1, O35.1XX2, O35.1XX3, O35.1XX4, O35.1XX5, and O35.1XX9 Supporting Information • Updated *Description of Services*, *Clinical Evidence*, and *References* sections to reflect the most current information	
Implanted Electrical Stimulator for Spinal Cord	Dec. 1, 2022	Coverage Rationale • Added language to indicate implanted electrical spinal cord	Implanted electrical spinal cord stimulators are proven and medically necessary for treating the following indications in certain circumstances, when performed according to U.S. Food and Drug Administration (FDA)

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Implanted Electrical Stimulator for Spinal Cord (continued)	Dec. 1, 2022	stimulators are unproven and not medically necessary for treating chronic intractable back pain without prior spine surgery due to insufficient evidence of efficacy **Supporting Information** • Updated *Clinical Evidence, FDA*, and *References* sections to reflect the most current information	labeled indications, contraindications, warnings, and precautions: • Complex regional pain syndrome (CRPS) • Painful lower limb diabetic neuropathy • Failed back surgery syndrome Implanted electrical spinal cord stimulators are unproven and not medically necessary for treating the following conditions due to insufficient evidence of efficacy: • Chronic intractable back pain without prior spine surgery • Refractory angina pectoris Dorsal root ganglion (DRG) stimulation is proven and medically necessary for treating refractory complex regional pain syndrome (CRPS I, CPRS II) in certain circumstances when performed according to U.S. Food and Drug Administration (FDA) labeled indications, contraindications, warnings, and precautions. Dorsal root ganglion (DRG) stimulation is unproven and not medically necessary for treating all other indications due to insufficient evidence of efficacy. For medical necessity clinical coverage criteria, refer to the InterQual® CP: Procedures, Spinal Cord Stimulator (SCS) Insertion. Click here to view the InterQual® criteria. Note: Coverage of a replacement battery/generator for a previously implanted electrical stimulator is appropriate when the individual's existing battery/generator is malfunctioning, cannot be repaired, and is no longer under warranty.
Lower Extremity Endovascular Procedures	Jan. 1, 2023	**Title Change** • Previously titled *Lower Extremity Invasive Diagnostic and*	Note: This policy does not apply to upper extremities. Endovascular revascularization procedures (e.g., stents, angioplasty and/or

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Lower Extremity Endovascular Procedures (continued)	Jan. 1, 2023	*Endovascular Procedures* Coverage Rationale • Removed language (and corresponding criteria) indicating lower extremity vascular angiography is proven and medically necessary for evaluating arterial disease, aneurysms, perivascular masses, and trauma related injuries of the lower extremity under certain circumstances • Added language to clarify endovascular revascularization procedures (e.g., stents, angioplasty and/or atherectomy) are proven and medically necessary for treating *non-limb-threatening* lower extremity ischemia in individuals with claudication due to atherosclerotic disease of the aortoiliac and/or femoropopliteal arteries when all of the [listed] criteria are met • Revised coverage guidelines for endovascular revascularization procedures (e.g., stents, angioplasty and/or atherectomy) for treating lower extremity Chronic Limb-Threatening Ischemia (CLTI); replaced indication-specific criteria with reference link to the diagnoses listed in the *Applicable*	atherectomy) are proven and medically necessary for treating non-limb-threatening lower extremity ischemia in individuals with Claudication due to atherosclerotic disease of the aortoiliac and/or femoropopliteal arteries when all the following criteria are met: • Impaired ability to work and/or perform activities of daily living (ADL); and • All the following conservative therapies have been tried and failed: ○ At least twelve (12) weeks of a Supervised or Structured Exercise Program; and ○ Pharmacologic therapy; and ○ Smoking cessation, if applicable and • Moderate to severe ischemic peripheral artery disease with Ankle-Brachial Index (ABI) ≤ 0.69; and • Imaging results show anatomic location and severity of occlusion (stenosis ≥ 50%) (e.g., duplex ultrasound, CTA, MRA or invasive angiography). If duplex ultrasound does not demonstrate a stenosis ≥ 50%, another imaging modality will be necessary to demonstrate the extent of stenosis. Endovascular revascularization procedures (e.g., stents, angioplasty and/or atherectomy) are proven and medically necessary for treating chronic limb threatening ischemia (CLTI) with the diagnoses listed in the *Applicable Codes* section of the policy. Due to insufficient evidence of efficacy, endovascular revascularization procedures (e.g., stents, angioplasty and/or atherectomy) for treating lower extremity ischemia are unproven and not medically necessary in the following circumstances: • Claudication due to isolated infrapopliteal (e.g., anterior tibial, posterior tibial or peroneal) artery disease • To prevent the progression of Claudication to CLTI • Individual is asymptomatic • Treatment of a nonviable limb

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**

Lower Extremity Endovascular Procedures (continued)	Jan. 1, 2023	*Codes* section of the policy
		Documentation Requirements
		• Updated list of HCPCS codes with associated documentation requirements:
		  ○ Added 37230 and 37231
		  ○ Removed 75710 and 75716
		• Updated list of *Required Clinical Information*:
		  ○ Replaced "documentation of *moderate to severe* ischemic peripheral artery disease using one of the following: Ankle-Brachial Index (ABI), *ankle pressure, Toe-Brachial Index (TBI), toe pressure, or transcutaneous oxygen pressure*" with "documentation of ischemic peripheral artery disease *including* Ankle-Brachial Index (ABI)"
		  ○ Removed documentation requirements for lower extremity vascular angiography
		Definitions
		• Removed definition of:
		  ○ Toe-Brachial Index (TBI)
		  ○ Transcutaneous Oxygen Pressure ($TcPO_2$)
		Applicable Codes
		• Removed CPT codes 75710 and 75716
		• Added list of applicable ICD-10	

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Lower Extremity Endovascular Procedures (continued)	Jan. 1, 2023	diagnosis codes: E08.52, E09.52, E10.52, E11.52, E13.52, I70.221, I70.222, I70.223, I70.228, I70.229, I70.231, I70.232, I70.233, I70.234, I70.235, I70.238, I70.239, I70.241, I70.242, I70.243, I70.244, I70.245, I70.248, I70.249, I70.25, I70.261, I70.262, I70.263, I70.268, I70.269, I70.321, I70.322, I70.323, I70.329, I70.331, I70.332, I70.333, I70.334, I70.335, I70.338, I70.339, I70.341, I70.342, I70.343, I70.344, I70.345, I70.348, I70.349, I70.35, I70.361, I70.362, I70.363, I70.369, I70.421, I70.422, I70.423, I70.428, I70.429, I70.431, I70.432, I70.433, I70.434, I70.435, I70.438, I70.439, I70.441, I70.442, I70.443, I70.444, I70.445, I70.448, I70.449, I70.461, I70.462, I70.463, I70.468, I70.469, I70.521, I70.522, I70.523, I70.528, I70.529, I70.531, I70.532, I70.533, I70.534, I70.535, I70.538, I70.539, I70.541, I70.542, I70.543, I70.544, I70.545, I70.548, I70.549, I70.561, I70.562, I70.563, I70.568, I70.569, I70.621, I70.622, I70.623, I70.628, I70.629, I70.631, I70.632, I70.633, I70.634, I70.635, I70.638, I70.639, I70.641, I70.642, I70.643, I70.644, I70.645, I70.648, I70.649, I70.661, I70.662, I70.663, I70.668, I70.669, I70.721, I70.722, I70.723, I70.728, I70.729,	

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Lower Extremity Endovascular Procedures (continued)	Jan. 1, 2023	I70.731, I70.732, I70.733, I70.734, I70.735, I70.738, I70.739, I70.741, I70.742, I70.743, I70.744, I70.745, I70.748, I70.749, I70.761, I70.762, I70.763, I70.768, I70.769, I72.3, I72.4, I72.8, I72.9, I73.00, I73.01, I73.1, I73.81, I74.3, I74.4, I74.5, I74.8, I74.9, I75.021, I75.022, I75.023, I75.029, I75.89, I77.2, I77.70, I77.72, I77.77, I77.79, I96, L03.115, L03.116, M86.051, M86.052, M86.059, M86.061, M86.062, M86.069, M86.071, M86.072, M86.079, M86.08, M86.09, M86.1, M86.10, M86.151, M86.152, M86.159, M86.161, M86.162, M86.169, M86.171, M86.172, M86.179, M86.18, M86.19, M86.20, M86.251, M86.252, M86.259, M86.261, M86.262, M86.269, M86.271, M86.272, M86.279, M86.28, M86.29, M86.30, M86.351, M86.352, M86.359, M86.361, M86.362, M86.369, M86.371, M86.372, M86.379, M86.38, M86.39, M86.40, M86.451, M86.452, M86.459, M86.461, M86.462, M86.469, M86.471, M86.472, M86.479, M86.48, M86.49, M86.50, M86.551, M86.552, M86.559, M86.561, M86.562, M86.571, M86.572,	

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Lower Extremity Endovascular Procedures (continued)	Jan. 1, 2023	M86.579, M86.58, M86.59, M86.60, M86.651, M86.652, M86.659, M86.661, M86.662, M86.669, M86.671, M86.672, M86.679, M86.68, M86.69, M86.8X0, M86.8X5, M86.8X6, M86.8X7, M86.8X8, M86.8X9, M86.9, Q27.30, Q27.32, Q27.39, Q27.8, Q27.9, Q87.2, S35.511A, S35.512A, S81.801A, S81.802A, S81.809A, S91.301A, S91.302A, S91.309A, T82.312A, T82.318A, T82.319A, T82.338A, T82.392A, T82.398A, T82.399A, T82.818A, T82.868A, and T82.898A **Supporting Information** • Updated *Clinical Evidence* and *References* sections to reflect the most current information	
Prostate Surgeries and Interventions	Dec. 1, 2022	**Coverage Rationale** • Added language to indicate: ○ High-energy water vapor thermotherapy for the treatment of benign prostatic hyperplasia (BPH) is proven and medically necessary when performed according to the following U.S. FDA labeled indications, contraindications, warnings, and precautions: ▪ To relieve symptoms, obstructions and reduce prostate tissue in men 50	Transurethral ablation of the prostate is proven and medically necessary in certain circumstances. For medical necessity clinical coverage criteria, refer to the InterQual® CP: Procedures, Prostatectomy, Transurethral Ablation. Click here to view the InterQual® criteria. Transurethral ablation of the prostate is unproven and not medically necessary for all other indications due to insufficient evidence of safety and/or efficacy. Cryoablation of the prostate is proven and medically necessary for recurrent prostate cancer diagnosed by biopsy. For medical necessity clinical coverage criteria, refer to the InterQual® CP: Procedures, Cryoablation, Prostate.

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Prostate Surgeries and Interventions (continued)	Dec. 1, 2022	years of age or older with a prostate volume ≥ 30 cm and ≤ 80 cm; or ▪ Treatment of the prostate with hyperplasia of the central zone and/or a median lobe ○ The following procedures are unproven and not medically necessary: ▪ Cryoablation of the prostate for initial treatment of prostate cancer ▪ Transperineal laser ablation (TPLA) ○ The following procedures are unproven and not medically necessary for all other indications [not listed in the policy as proven and medically necessary] due to insufficient evidence of safety and/or efficacy: ▪ Cryoablation of the prostate ▪ High-energy water vapor thermotherapy ▪ Prostatic urethral lift (PUL) ▪ Surgical prostatectomy ▪ Transurethral ablation of the prostate • Replaced language indicating:	Click here to view the InterQual® criteria. Cryoablation of the prostate is unproven and not medically necessary for initial treatment of prostate cancer and for all other indications due to insufficient evidence of safety and/or efficacy. Surgical prostatectomy is proven and medically necessary in certain circumstances, including for some individuals with very high risk or recurrent prostate cancer. For medical necessity clinical coverage criteria, refer to the InterQual® CP: Procedures, Prostatectomy, Radical. Click here to view the InterQual® criteria. Surgical prostatectomy is unproven and not medically necessary for all other indications due to insufficient evidence of safety and/or efficacy. Prostatic urethral lift (PUL) is proven and medically necessary when performed according to the following U.S. Food and Drug Administration (FDA) labeled indications, contraindications, warning and precautions: • Treating symptoms due to urinary outflow obstruction secondary to benign prostatic hyperplasia (BPH), including lateral and median lobe hyperplasia; in men 45 years of age or older, and • The following are not present: ○ Prostate volume of > 100 cc ○ A urinary tract infection ○ Urethra conditions that may prevent insertion of delivery system into bladder ○ Urinary incontinence due to incompetent sphincter ○ Current gross hematuria Prostatic urethral lift (PUL) is unproven and not medically necessary for all other indications due to insufficient evidence of safety and/or efficacy.

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Prostate Surgeries and Interventions (continued)	Dec. 1, 2022	○ "Cryoablation of the prostate is proven and medically necessary *in certain circumstances*" with "cryoablation of the prostate is proven and medically necessary for *recurrent prostate cancer diagnosed by biopsy*" ○ "Surgical prostatectomy is proven and medically necessary in certain circumstances" with "surgical prostatectomy is proven and medically necessary in certain circumstances, *including for some individuals with very high risk or recurrent prostate cancer*" ○ "Prostatic urethral lift (PUL) is proven and medically necessary when performed according to the following U.S. FDA labeled indication" with "prostatic urethral lift (PUL) is proven and medically necessary when performed according to the following U.S. FDA labeled indications, *contraindications, warnings, and precautions*" ○ "Focal laser ablation is unproven and not medically	High-energy water vapor thermotherapy for the treatment of benign prostatic hyperplasia (BPH) is proven and medically necessary when performed according to the following U.S. Food and Drug Administration (FDA) labeled indications, contraindications, warning and precautions: • To relieve symptoms, obstructions and reduce prostate tissue in men 50 years of age or older with a prostate volume ≥ 30 cm and ≤ 80 cm, or • Treatment of the prostate with hyperplasia of the central zone and/or a median lobe High-energy water vapor thermotherapy for the treatment of BPH in circumstances not listed above or for the treatment of malignant prostate tissue is unproven and not medically necessary due to insufficient evidence of safety and/or efficacy. The transperineal placement of biodegradable material, peri-prostatic (via needle) is proven and medically necessary for use with radiotherapy for treating prostate cancer. The transperineal placement of biodegradable material, peri-prostatic (via needle) is unproven and not medically necessary for all other indications due to insufficient evidence of safety and/or efficacy. The following procedures are unproven and not medically necessary due to insufficient evidence of safety and/or efficacy: • Transperineal focal laser ablation • Insertion of a temporary prostatic urethral stent • Transperineal laser ablation (TPLA) • Transurethral waterjet ablation of the prostate (aquablation) • Vascular embolization

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**

Prostate Surgeries and Interventions (continued)	Dec. 1, 2022	necessary" with "*transperineal* focal laser ablation is unproven and not medically necessary"
		Documentation Requirements
		• Updated list of CPT codes with associated documentation requirements:
		  ○ Added 37243
		  ○ Removed 53852 and 55873
		• Updated list of *Required Clinical Information* to reflect/include:
		  ○ Diagnosis, including:
		  ▪ Cancer risk group, including stage of disease
		  ▪ Life expectancy
		  ▪ Results of diagnostic prostate biopsy
		  ○ History of the medical condition(s) requiring treatment or surgical intervention, including dates
		  ○ Documentation of signs and symptoms; including onset, duration, and frequency
		  ○ Physical exam, including result of digital rectal exam
		  ○ Relevant medical history, including:
		  ▪ List of current patient medication
		  ▪ History of hematuria
		  ▪ History of urinary incontinence	

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Prostate Surgeries and Interventions (continued)	Dec. 1, 2022	▪ Current urinary tract infection ▪ Allergy to nickel ○ Treatments tried, failed, or contraindicated; include the dates, duration, and reason for discontinuation ○ Relevant surgical history, including dates ○ Reports of all recent imaging studies and applicable diagnostics including: ▪ Results of uroflow test [Q-max and postvoid residual (PVR) test] ▪ Results of urinalysis ▪ Results of PSA test ▪ Results of prostate biopsies ▪ Results of prostate volume via transrectal ultrasound (TRUS) ▪ Prostate volume ▪ Presence of signs or symptoms of obstruction ▪ Presence of protruding median lobe of the prostate ○ Physician treatment plan/surgical plan, including plans for pelvic lymph node dissection and radiotherapy Applicable Codes	

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Prostate Surgeries and Interventions (continued)	Dec. 1, 2022	• Added CPT code 0714T **Supporting Information** • Updated *Description of* Services, *Clinical Evidence*, *FDA*, and *References* sections to reflect the most current information	

Spinal Fusion and Bone Healing Enhancement Products	Dec. 1, 2022	**Title Change**
		• Previously titled *Spinal Fusion Enhancement Products*
		Coverage Rationale
		• Revised list of products that are proven and medically necessary for the enhancement of spinal fusion; replaced "the InFUSE/MASTERGRAFT™ Posterolateral Revision Device System (or InFUSE BMP used with MASTERGRAFT) when used according to U.S. FDA indications in individuals who meet all of the [listed] criteria" with "the InFUSE/MASTERGRAFT™ Posterolateral Revision Device System (or InFUSE BMP used with MASTERGRAFT) when used according to U.S. FDA indications, *contraindications, warnings, and precautions* in individuals who meet all of the [listed] criteria"
		• Replaced language indicating "the [listed products] are unproven and not medically necessary for the enhancement of spinal fusion due
			The following are proven and medically necessary for the enhancement of spinal fusion:
			• Autografts (including Bone Marrow Aspirate used for bone grafting)
			• Demineralized Bone Matrix (DBM) without added products listed below as unproven and not medically necessary
			• Allograft-based products not listed below as unproven and not medically necessary
			• InFUSE® Bone Graft (Recombinant human bone morphogenetic protein-2 (rhBMP-2) of the lumbar spine when the following criteria are met:
			  ○ The approach is anterior or oblique and used in conjunction with an FDA-approved interbody fusion device
			  ○ Skeletally mature individual (18 years of age or older or radiographic evidence of epiphyseal closure) with degenerative disc disease (DDD)
			  ○ The fusion involves vertebral bodies L2-S1, without or with spondylolisthesis of no more than grade 1 (25% displacement) at the involved level
			  ○ The fusion is single level
			• The InFUSE/MASTERGRAFT™ Posterolateral Revision Device System (or InFUSE BMP used with MASTERGRAFT) when used according to U.S. Food and Drug Administration (FDA) indications, contraindications, warnings and precautions in individuals who meet all of the following criteria:
			  ○ Implanted via a posterolateral approach
			  ○ Presence of symptomatic posterolateral lumbar spine pseudoarthrosis
			  ○ Skeletally mature patient (older than 21 years of age or radiographic evidence of epiphyseal closure)
			  ○ Autologous bone and/or bone marrow harvest is not feasible or is not expected to promote fusion

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Spinal Fusion and Bone Healing Enhancement Products (continued)	Dec. 1, 2022	to insufficient evidence of efficacy" with "the [listed products] are unproven and not medically necessary for the enhancement of spinal fusion *and bone healing* due to insufficient evidence of efficacy *and/or safety*" • Revised list of products that are unproven and not medically necessary; replaced: ○ "Human amniotic tissue materials, including amniotic fluid stem cell substitutes *for the treatment of spine disease or in spine surgery*" with "human amniotic tissue materials, including amniotic fluid stem cell substitutes" ○ "*OptiMesh*® Expandable Interbody Fusion System" with "Expandable Interbody Fusion System" Definitions • Added definition of: ○ Bioactive Glass ○ Duo™ Ti Expandable Interbody Fusion System • Removed definition of: ○ Anorganic Bone Graft Materials ○ Carrier Systems ○ Cell-Based Products ○ Combination Bone Graft	The following are unproven and not medically necessary for the enhancement of spinal fusion and bone healing due to insufficient evidence of efficacy and/or safety: • Allograft based products: ○ Cell-based (e.g., mesenchymal stem cells (MSC) ○ Human amniotic tissue materials, including amniotic fluid stem cell substitutes ○ Recombinant human bone morphogenetic protein-2 (e.g., rhBMP-2, InFUSE) and InFUSE/MASTERGRAFT™ (or InFUSE BMP used with Mastergraft or Mastergraft alone) Posterolateral Revision Device for all other indications not included above • Ceramic-Based Products (e.g., beta tricalcium phosphate (b-TCP), calcium phosphate, calcium sulfate) used alone or in combination with other grafts including Bone Marrow Aspirate • Bioactive Glass used alone or in combination with other grafts including Bone Marrow Aspirate • Expandable Interbody Fusion System

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Spinal Fusion and Bone Healing Enhancement Products (continued)	Dec. 1, 2022	Substitutes ○ Orthobiologics • Updated definition of: ○ Allograft ○ Autograft ○ Bone Marrow Aspirate ○ Bone Morphogenetic Proteins (BMP) and Recombinant Human Bone Morphogenetic Proteins (rhBMP) ○ Ceramic-Based Products ○ Demineralized Bone Matrix (DBM) ○ Human Amniotic Tissue Membrane ○ InFUSE™ Bone Graft ○ OptiMesh® Expandable Interbody Fusion System® **Supporting Information** • Updated *Description of Services*, *Clinical Evidence*, *FDA*, and *References* sections to reflect the most current information	
Total Artificial Disc Replacement for the Spine	Nov. 1, 2022	**Coverage Rationale** • Added language to indicate cervical artificial disc replacement with an FDA-approved prosthetic intervertebral disc is proven and medically necessary for treating one level or two contiguous levels of cervical Degenerative Disc Disease, in a Skeletally Mature individual with a history of cervical	Cervical artificial total disc replacement with an FDA-approved prosthetic intervertebral disc is proven and medically necessary for treating one-level or two contiguous levels of cervical Degenerative Disc Disease (C3 to C7), in a Skeletally Mature individual with symptomatic radiculopathy and/or myelopathy. Cervical artificial disc replacement with an FDA-approved prosthetic intervertebral disc is proven and medically necessary for treating one level or two contiguous levels of cervical Degenerative Disc Disease, in a Skeletally Mature individual with a history of cervical spinal fusion at another level

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Total Artificial Disc Replacement for the Spine (continued)	Nov. 1, 2022	spinal fusion at another level (adjacent or non-adjacent) **Supporting Information** • Updated *Clinical Evidence* and *References* sections to reflect the most current information	(adjacent or non-adjacent). For medical necessity clinical coverage criteria, refer to the InterQual® CP: Procedures, Artificial Disc Replacement, Cervical. Click here to view the InterQual® criteria. Cervical artificial disc replacement at one level combined with cervical spinal fusion surgery at another level (adjacent or non-adjacent), as part of the same surgical plan, is unproven and not medically necessary due to insufficient evidence of efficacy. Lumbar artificial total disc replacement with an FDA-approved prosthetic intervertebral disc is proven and medically necessary for treating single level lumbar Degenerative Disc Disease with symptomatic intractable discogenic low back pain in a Skeletally Mature individual when there are no contraindications. Contraindications to lumbar artificial total disc replacement include but are not limited to the following: • Moderate or severe facet arthropathy or pars defect at the operative level on a preoperative MRI scan, CT scan or plain radiograph • Lumbosacral spinal fracture • Scoliosis of the lumbosacral spine • Active systemic infection or infection localized to the site of implantation • Tumor in the peritoneum, retroperitoneum or site of implantation • Osteoporosis or osteopenia as defined by recent (within one year) DEXA scan • Isolated radicular compression syndromes, especially due to disc herniation • Spinal stenosis or radiculopathy • Previous lumbar spine surgery where the previous surgery destabilized the spine or where the spine at the level of the previous surgery is an alternate source of pain

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Total Artificial Disc Replacement for the Spine (continued)	Nov. 1, 2022		• Vascular, urological, or other peritoneal or retroperitoneal pathology that may preclude safe and adequate anterior spine exposure as required for the surgery For medical necessity clinical coverage criteria, refer to the InterQual® Client Defined, CP: Procedures, Artificial Disc Replacement, Lumbar (Custom) - UHG. Click here to view the InterQual® criteria. Lumbar artificial total disc replacement is unproven and not medically necessary in the following situations due to insufficient evidence of efficacy: • More than one spinal level • Prior history of lumbar fusion or when combined with a lumbar fusion at any level • Treating any other indications not listed above

Updated

Policy Title	Effective Date	Summary of Changes
Skyrizi® (Risankizumab-Rzaa)	Nov. 1, 2022	Coverage Rationale • Removed reference link to the Medical Benefit Drug Policy titled *Review at Launch for New to Market Medications* (prior authorization effective Nov. 1, 2022)

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Alpha1-Proteinase Inhibitors	Nov. 1, 2022	Coverage Rationale • Revised coverage criteria for continuation of therapy: ○ Added criterion requiring: ▪ Patient is currently receiving therapy for emphysema due to congenital alpha$_1$-antitrypsin (AAT) deficiency ○ Removed criterion requiring: ▪ Diagnosis of congenital alpha1-antitrypsin deficiency confirmed by one of the following: – Pi*ZZ, Pi*Z(null) or Pi*(null)(null) protein phenotypes (homozygous); or – Other rare AAT disease-causing alleles associated with serum alpha1-antitrypsin (AAT) level < 11 µmol/L [e.g., Pi (Malton, Malton)] ▪ Diagnosis of emphysema confirmed with pulmonary	Alpha$_1$-proteinase inhibitors (Aralast NP™, Glassia™, Prolastin®-C, and Zemaira®) are proven for chronic augmentation and maintenance therapy of patients with emphysema due to congenital deficiency of alpha$_1$-proteinase inhibitor (A$_1$-PI), also known as alpha$_1$-antitrypsin (AAT) deficiency. Alpha$_1$-proteinase inhibitors (Aralast NP™, Glassia™, Prolastin®-C, and Zemaira®) are medically necessary for the treatment of emphysema due to congenital deficiency of alpha$_1$-proteinase inhibitor (A$_1$-PI) in patients who meet all of the following criteria: • For initial therapy, all of the following: ○ Diagnosis of congenital alpha1-antitrypsin deficiency confirmed by one of the following: ▪ Pi*ZZ, Pi*Z(null) or Pi*(null)(null) protein phenotypes (homozygous); or ▪ Other rare AAT disease-causing alleles associated with serum alpha$_1$-antitrypsin (AAT) level < 11 µmol/L [e.g., Pi (Malton, Malton)] and ○ Circulating serum concentration of alpha$_1$-antitrypsin (AAT) level < 11 µmol/L (which corresponds to < 80 mg/dl if measured by radial immunodiffusion or < 57 mg/dl if measured by nephelometry); and ○ Continued optimal conventional treatment for emphysema (e.g., bronchodilators, supplemental oxygen if necessary); and ○ Current nonsmoker; and ○ Diagnosis of emphysema confirmed with pulmonary function testing; and ○ Dosing is in accordance with the United States Food and Drug Administration approved labeling; and ○ Initial authorization will be for no more than 12 months.

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Alpha1-Proteinase Inhibitors (continued)	Nov. 1, 2022	function testing ○ Replaced criterion requiring: ▪ "*Submission of medical records (e.g., chart notes, laboratory values) documenting* a positive clinical response *from pretreatment baseline to alpha1-proteinase inhibitor treatment*" with "*documentation of* a positive clinical response (*e.g., decreased frequency of exacerbations, improvement in symptom burden, slowed rate of FEV_1*)" ▪ "Current nonsmoker" with "patient remains a nonsmoker" **Supporting Information** ● Updated *References* section to reflect the most current information	● For continuation therapy, all of the following: ○ Patient is currently receiving therapy for emphysema due to congenital $alpha_1$-antitrypsin (AAT) deficiency; and ○ Documentation of a positive clinical response (e.g., decreased frequency of exacerbations, improvement in symptom burden, slowed rate of FEV_1); and ○ Patient remains a nonsmoker; and ○ Dosing is in accordance with the United States Food and Drug Administration approved labeling; and ○ Reauthorization will be for no more than 12 months. $Alpha_1$-proteinase inhibitor is unproven for: ● Conditions other than emphysema associated with alpha1-antitrypsin deficiency ● Cystic fibrosis
Drug Coverage Criteria - New and Therapeutic Equivalent Medications (for Oxford Only)	Nov. 1, 2022	**Coverage Rationale** ● Revised list of medications requiring prior authorization through the pharmacy benefit manager (PBM); removed Qelbree	Refer to the policy for complete details.
Gonadotropin Releasing Hormone Analogs	Oct. 1, 2022	**Coverage Rationale** ● Revised list of applicable gonadotropin releasing hormone analog (GnRH analog) drug	Refer to the policy for complete details.

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Gonadotropin Releasing Hormone Analogs (continued)	Oct. 1, 2022	products; removed: ○ Lupaneta Pack™ (leuprolide acetate injection & norethindrone acetate tablets) (discontinued) ○ Vantas® (histrelin acetate) (discontinued) • Removed language indicating: ○ Lupaneta Pack is proven and medically necessary for the treatment of endometriosis ○ Vantas is proven and medically necessary for the treatment of central Precocious Puberty ○ Zoladex is not recommended for the retreatment of endometriosis, per FDA labeling **Applicable Codes** • Removed HCPCS code J9225 • Updated list of applicable ICD-10 diagnosis codes to reflect annual edits: ○ Added N80.00, N80.01, N80.02, N80.03, N80.101, N80.102, N80.103, N80.109, N80.111, N80.112, N80.113, N80.119, N80.121, N80.122, N80.123, N80.129, N80.201, N80.202, N80.203, N80.209, N80.211, N80.212, N80.213, N80.219, N80.221, N80.222, N80.223, N80.229, N80.30,	

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Gonadotropin Releasing Hormone Analogs (continued)	Oct. 1, 2022	N80.311, N80.312, N80.319, N80.321, N80.322, N80.329, N80.331, N80.332, N80.333, N80.339, N80.341, N80.342, N80.343, N80.349, N80.351, N80.352, N80.353, N80.359, N80.361, N80.362, N80.363, N80.369, N80.371, N80.372, N80.373, N80.379, N80.381, N80.382, N80.383, N80.389, N80.391, N80.392, N80.399, N80.3A1, N80.3A2, N80.3A3, N80.3A9, N80.3B1, N80.3B2, N80.3B3, N80.3B9, N80.3C1, N80.3C2, N80.3C3, N80.3C9, N80.40, N80.41, N80.42, N80.50, N80.511, N80.512, , 80.519, N80.521, N80.522, N80.529, N80.531, N80.532, N80.539, N80.541, N80.542, N80.549, N80.551, N80.552, N80.559, N80.561, N80.562, N80.569, N80.A0, N80.A1, N80.A2, N80.A41, N80.A42, N80.A43, N80.A49, N80.A51, N80.A52, N80.A53, N80.A59, N80.A61, N80.A62, N80.A63, N80.A69, N80.B1, N80.B2, N80.B31, N80.B32, N80.B39, N80.B4, N80.B5, N80.B6, N80.C0, N80.C10, N80.C11, N80.C19, N80.C2, N80.C3, N80.C4, N80.C9, N80.D0,	

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Gonadotropin Releasing Hormone Analogs (continued)	Oct. 1, 2022	N80.D1, N80.D2, N80.D3, N80.D4, N80.D5, N80.D6, and N80.D9 ○ Removed N80.0, N80.1, N80.2, N80.3, and N80.4 **Supporting Information** ● Updated *Background*, *Clinical Evidence*, *FDA*, and *References* sections to reflect the most current information	
Leqvio® (Inclisiran)	Nov. 1, 2022	**Related Policies** ● Removed reference link to the Medical Benefit Drug Policy titled *Provider Administered Drugs – Site of Care* **Coverage Rationale** ● Revised coverage criteria for initial therapy; removed criterion requiring one of the following: ○ Despite adherence to PCSK9 therapy (defined by at least 12 consecutive weeks of use), one of the following: ▪ Both of the following: – Patient has clinical ASCVD; and – Patient failed to achieve LDL-C goal of < 70 mg/dL ▪ Both of the following: – Patient has severe heterozygous familial hypercholesterolemia	Leqvio (inclisiran) is proven and medically necessary for the treatment of heterozygous familial hypercholesterolemia (HeFH) or clinical atherosclerotic cardiovascular disease (ASCVD) in patients who meet all of the following criteria: ● For initial therapy, all of the following: ○ Diagnosis of one of the following: ▪ Heterozygous familial hypercholesterolemia (HeFH) as confirmed by one of the following*: – Both of the following: • Pre-treatment LDL-C greater than or equal to 190 mg/dL (greater than or equal to 155 mg/dL if less than 16 years of age); and • One of the following: ○ Family history of myocardial infarction in first-degree relative < 60 years of age; or ○ Family history of myocardial infarction in second-degree relative < 50 years of age; or ○ Family history of LDL-C greater than or equal to 190 mg/dL in first- or second-degree relative; or ○ Family history of heterozygous or homozygous familial hypercholesterolemia in first- or second-degree relative; or ○ Family history of tendinous xanthomata and/or arcus

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Leqvio® (Inclisiran) (continued)	Nov. 1, 2022	(HeFH) (pre-treatment LDL-C ≥ 190 mg/dL); and – Patient failed to achieve LDL-C goal of < 100 mg/dL ○ Patient has a history of intolerance or contraindication to PCSK9 therapy	cornealis in first- or second degree relative or – Both of the following: • Pre-treatment LDL-C greater than or equal to 190 mg/dL (greater than or equal to 155 mg/dL if less than 16 years of age); and • One of the following: ○ Functional mutation in LDL, apoB, or PCSK9 gene*; or ○ Tendinous xanthomata; or ○ Arcus cornealis before age 45 or ▪ Atherosclerotic cardiovascular disease (ASCVD) as confirmed by one of the following: – Acute coronary syndromes; or – History of myocardial infarction; or – Coronary or other arterial revascularization; or – Stroke; or – Transient ischemic attack; or – Peripheral arterial disease presumed to be of atherosclerotic origin and ○ Prescribed by a lipid specialist (e.g., cardiologist, endocrinologist, lipid specialist/lipidologist); and ○ Patient will continue other traditional low-density lipoprotein-cholesterol (LDL-C) lowering therapies (e.g., maximally tolerated statins, ezetimibe) in combination with Leqvio; and ○ Leqvio will not be used in combination with PCSK9 inhibitor therapy; and ○ Leqvio dosing is in accordance with the United States Food and Drug Administration approved labeling; and ○ Initial authorization will be for no more than 12 months. • For continuation of therapy, all of the following: ○ Documentation of a positive clinical response to therapy from pre-

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Leqvio® (Inclisiran) (continued)	Nov. 1, 2022		treatment baseline (e.g., achieved LDL-C goal of < 100 mg/dL or achieved a 50% reduction in LDL-C levels); and ○ Patient continues treatment with other traditional low-density lipoprotein-cholesterol (LDL-C) lowering therapies (e.g., statin, ezetimibe) in combination with Leqvio; and ○ Leqvio will not be used in combination with PCSK9 therapy; and ○ Leqvio dosing is in accordance with the United States Food and Drug Administration approved labeling; and ○ Reauthorization will be for no more than 12 months. *Results of prior genetic testing can be submitted as confirmation of diagnosis of HeFH, however please note that UnitedHealthcare does not currently cover genetic testing for evidence of an LDL-receptor mutation, familial defective apo B-100 or a PCSK9 mutation.
Maximum Dosage and Frequency	Nov. 1, 2022	Coverage Rationale ● Revised list of medications requiring administration by a medical professional: ○ Added (with corresponding maximum dosage and frequency limitations): ▪ Atezolizumab (Tecentriq®) ▪ Avelumab (Bavencio®) ▪ Bevacizumab-Maly (Alymsys®) ▪ Cemiplimab-Rwlc (Libtayo®) ▪ Durvalumab (Imfinzi®) ▪ Ipilimumab (Yervoy®) ▪ Pembrolizumab (Keytruda®) ▪ Rituximab-Arrx (Riabni™) ○ Removed Zometa®	This policy provides information about the maximum dosage per administration and dosing frequency for certain medications administered by a medical professional. Most medications have a maximum dosage and frequency based upon body surface area or patient weight or a set maximal dosage and frequency independent of patient body size. **Drug Products** ● abatacept (Orencia®) ● aflibercept (Eylea®) ● atezolizumab (Tecentriq®) ● avelumab (Bavencio®) ● bevacizumab (Avastin®) ● bevacizumab-awwb (Mvasi™) ● bevacizumab-bvzr (Zirabev®) ● bevacizumab-maly (Alymsys®) ● brolucizumab-dbll (Beovu®) ● cemiplimab-rwlc (Libtayo®) ● certolizumab pegol (Cimzia®) ● denosumab (Prolia® & Xgeva®)

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Maximum Dosage and Frequency (continued)	Nov. 1, 2022	• Updated language pertaining to body weight and surface area measurements to reflect the most recent clinical evidence *Maximum Allowed Quantities by HCPCS Units* • Revised list of applicable medications: ○ Added: ▪ Bavencio (avelumab) ▪ Imfinzi (durvalumab) ▪ Keytruda (pembrolizumab) ▪ Libtayo (cemiplimab-rwlc) ▪ Riabni (rituximab-arrx) ▪ Tecentriq (atezolizumab) ▪ Yervoy (ipilimumab) ○ Removed Zometa® • Updated *Maximum Allowed* units for: ○ Avastin ○ Avsola ○ Hemlibra ○ Herceptin ○ Herzuma ○ Inflectra ○ Kanjinti ○ Mvasi ○ Ogivri ○ Ontruzant ○ Remicade ○ Renflexis ○ Rituxan ○ Ruxience	• durvalumab (Imfinzi®) • eculizumab (Soliris®) • emicizumab-kxwh (Hemlibra®) • golimumab (Simponi Aria®) • infliximab (Remicade®) • infliximab-axxq (Avsola™) • infliximab-dyyb (Inflectra®) • infliximab-abda (Renflexis®) • ipilimumab (Yervoy®) • nivolumab (Opdivo®) • omalizumab (Xolair®) • patisiran (Onpattro®) • pegaptanib sodium (Macugen®) • pegfilgrastim (Neulasta®) • pegfilgrastim-apgf (Nyvepria™) • pegfilgrastim-cbqv (Udenyca®) • pegfilgrastim-jmdb (Fulphila™) • pegfilgrastim-bmez (Ziextenzo®) • pembrolizumab (Keytruda®) • ranibizumab (Lucentis®) • ravulizumab-cwvz (Ultomiris®) • rituximab (Rituxan®) • rituximab-pvvr (Ruxience™) • rituximab-abbs (Truxima®) • rituximab-arrx (Riabni™) • rituximab and hyaluronidase (Rituxan Hycela®) • testosterone cypionate (Depo-Testosterone®) • testosterone enanthate • testosterone pellets (Testopel®) • testosterone undecanoate (Aveed®) • tildrakizumab-asmn (Ilumya™) • tocilizumab (Actemra®) • trastuzumab (Herceptin®)

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Maximum Dosage and Frequency (continued)	Nov. 1, 2022	○ Trazimera ○ Truxima ○ Zirabev • Updated *Maximum Dosage per Administration* for: ○ Rituxan ○ Ruxience ○ Truxima • Added applicable diagnoses for zoledronic acid: ○ Oncology/hypercalcemia (4 mg) ○ Osteoporosis/Paget's disease (5 mg) *Maximum Allowed Quantities for National Drug Code (NDC) Billing* • Revised list of applicable medications: ○ Added: ▪ Alymsys (bevacizumab-maly) ▪ Bavencio (avelumab) ▪ Imfinzi (durvalumab) ▪ Keytruda (pembrolizumab) ▪ Libtayo (cemiplimab-rwlc) ▪ Riabni (rituximab-arrx) ▪ Tecentriq (atezolizumab) ▪ Yervoy (ipilimumab) ○ Removed Zometa® • Updated applicable NDCs for: ○ Actemra: Added 50242-0138-01 and 50242-0143-01	• trastuzumab-anns (Kanjinti™) • trastuzumab-dkst (Ogivri™) • trastuzumab-dttb (Ontruzant®) • trastuzumab-pkrb (Herzuma®) • trastuzumab-qyyp (Trazimera™) • ustekinumab (Stelara®) • vedolizumab (Entyvio®) • zoledronic acid (zoledronic acid, Reclast®) The use of medications included in this policy when given within the maximum dosage and/or frequency based upon body surface area or patient weight or a set of maximal dosage and/or frequency independent of patient body size are proven when used according to labeled indications or when otherwise supported by published clinical evidence. The medications included in this policy when given beyond maximum dosages and/or frequency based upon body surface area or patient weight or a set maximal dosage independent of patient body size are not supported by package labeling or published clinical evidence and are unproven. This policy creates an upper dose limit based on the clinical evidence and the 95th percentile for adult body weight (140 kg) and body surface area (2.71 meters^2) in the U.S. (adult male, 30 to 39 years, Fryar, 2021). In some cases, the maximum allowed units and/or vials may exceed the upper level limit as defined within this policy due to an individual patient body weight > 140 kg or body surface area > 2.71 meters^2. Refer to the policy for complete details.

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Maximum Dosage and Frequency (continued)	Nov. 1, 2022	○ Ilumya: Removed 47335-0177-96, 47335-0177-01, and 47335-0177-10 ○ Opdivo: Added 00003-3756-14 ○ Ultomiris: ▪ Added 25682-0028-01 and 25682-0025-01 ▪ Removed 25682-0022-01 ○ Xolair: ▪ Added 50242-0040-62 ▪ Removed 50242-0040-86 and 50242-0215-86 ● Updated *Maximum Allowed* units for: ○ Avastin ○ Avsola ○ Hemlibra ○ Herceptin ○ Inflectra ○ Mvasi ○ Remicade ○ Renflexis ○ Rituxan ○ Ruxience ○ Truxima ○ Zirabev *Maximum Allowed Frequencies* ● Revised list of applicable medications: ○ Added: ▪ Alymsys (bevacizumab-maly) ▪ Bavencio (avelumab)	

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Maximum Dosage and Frequency (continued)	Nov. 1, 2022	▪ Byooviz (ranibizumab-nuna) ▪ Herceptin (trastuzumab) ▪ Herzuma (trastuzumab-pkrb) ▪ Imfinzi (durvalumab) ▪ Kanjinti (trastuzumab-anns) ▪ Keytruda (pembrolizumab) ▪ Libtayo (cemiplimab-rwlc) ▪ Mvasi (bevacizumab-awwb) ▪ Ogivri (trastuzumab-dkst) ▪ Ontruzant (trastuzumab-dttb) ▪ Tecentriq (atezolizumab) ▪ Trazimera (trastuzumab-qyyp) ▪ Vabysmo (faricimab) ▪ Yervoy (ipilimumab) ▪ Zirabev (bevacizumab-bvzr) • Added *Maximum Frequency* guidelines for: ○ Actemra for the diagnosis of "cytokine release syndrome, Chimeric antigen receptor T-cell induced, severe or life-threatening disease" ○ Avastin for the diagnosis of "oncology" ○ Beovu for the diagnosis of "diabetic macular edema"	

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Maximum Dosage and Frequency (continued)	Nov. 1, 2022	○ Orencia for the diagnosis of "graft-versus-host disease (GVHD) prophylaxis" ○ Ultomiris for the diagnosis of "myasthenia gravis (MG)" ○ Xgeva for the diagnosis of "hypercalcemia of malignancy" ● Revised *Maximum Frequency* guidelines for: ○ Avsola, Inflectra, Remicade, and Renflexis for the diagnosis of "sarcoidosis": Replaced "administered at 0, 2, and *6* weeks, then every *8* weeks thereafter" with "administered at week 0 and 2, then once every *4 to 6* weeks thereafter" ○ Hemlibra: Added language to clarify the listed *Maximum Frequency* guidelines apply to the diagnosis of "hemophilia A" ○ Orencia for the diagnoses of "JIA, psoriatic arthritis, rheumatoid arthritis": Replaced "administered at 0, 2, and 4 weeks, then once every 4 weeks thereafter" with "administered *intravenously* at 0, 2, and 4 weeks, then once every 4 weeks thereafter; *administered subcutaneously once weekly*"	

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Maximum Dosage and Frequency (continued)	Nov. 1, 2022	○ Ultomiris: Replaced "administered initially, week 2, then once every 8 weeks thereafter" with "administered initially, week 2, then once every *4 or* 8 weeks thereafter, *depending on body weight*" **Applicable Codes** ● Added HCPCS codes J9022, J9023, J9119, J9173, J9228, J9271, and Q5123 ● Added NDCs 00003-2327-11, 00003-2328-22, 00003-3756-14, 00006-3026-01, 00006-3026-02, 00006-3026-04, 00006-3029-01, 00006-3029-02, 00310-4500-12, 00310-4611-50, 25682-0025-01, 25682-0028-01, 44087-3535-01, 50242-0138-01, 50242-0143-01, 50242-0917-01, 50242-0918-01, 55513-0224-01, 55513-0326-01, 61755-0008-01, 70121-1754-01, 70121-1754-07, 70121-1755-01, and 70121-1755-07 ● Removed NDCs 25682-0022-01, 47335-0177-96, 50242-0040-86, and 50242-0215-86 **Supporting Information** ● Updated *Clinical Evidence* and *References* sections to reflect the most current information	

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Xolair® (Omalizumab)	Nov. 1, 2022	Coverage Rationale *Nasal Polyps* Proven • Revised coverage criteria; replaced criterion requiring "patient has had inadequate response to nasal corticosteroids [e.g., Flonase® (fluticasone), *Rhinocort® (budesonide)*, *Nasonex®* (mometasone)]" with "patient has had inadequate response to nasal corticosteroids [e.g., fluticasone, mometasone, *triamcinolone*]" Medically Necessary • Revised coverage criteria for initial therapy: ○ Removed criterion requiring the presence of bilateral nasal polyposis or the patient has previously required surgical removal of bilateral nasal polyps ○ Replaced criterion requiring: ▪ "Diagnosis of *chronic rhinosinusitis with* nasal polyps *(CRSwNP) defined by all of the [listed criteria]*" with "diagnosis of nasal polyps" ▪ "Patient has required systemic corticosteroids (e.g., prednisone, methylprednisolone) for	This policy refers to Xolair (omalizumab) subcutaneous injection for administration by a healthcare professional. Xolair (omalizumab) for self-administered subcutaneous injection is obtained under the pharmacy benefit. Refer to the policy for complete details.

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Xolair® (Omalizumab) (continued)	Nov. 1, 2022	*CRSwNP* in the previous 2 years" with "patient has required systemic corticosteroids (e.g., prednisone, methylprednisolone) for *nasal polyps* in the previous 2 years" ▪ "Patient has been unable to obtain symptom relief after trial of *two* of the following *classes of agents*: nasal saline irrigations, intranasal corticosteroids (e.g., fluticasone, mometasone, triamcinolone), antileukotriene agents (e.g., montelukast, zafirlukast, zileuton)" with "patient has been unable to obtain symptom relief after trial of *both* of the following: intranasal corticosteroids (e.g., fluticasone, mometasone, triamcinolone) *and one other therapy used in the management of nasal polyps [i.e.,* nasal saline irrigations, antileukotriene agents (e.g., montelukast, zafirlukast, zileuton)]"	

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Xolair® (Omalizumab) (continued)	Nov. 1, 2022	• Updated list of examples of anti-interleukin-5 therapy drug products the patient cannot receive in combination with Xolair; added Nucala (mepolizumab) Supporting Information • Updated *References* section to reflect the most current information	

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Private Duty Nursing Services	Nov. 1, 2022	Coverage Rationale *Requirements for Coverage* • Replaced language indicating "Private Duty Nursing services are covered and considered Medically Necessary [when criteria are met]" with "*when benefits are available*, Private Duty Nursing services are covered and considered Medically Necessary [when criteria are met]" • Revised coverage criteria; added criterion requiring: ○ Face-to-face visit with the patient within 90 days prior to the start of care, or within 30 days after the start of care ○ Home care agency can safely deliver the required care at home ○ Home environment is safe, accessible, and can be modified to accommodate the home care plan *Documentation Requirements* • Updated list of required clinical documentation for: Initial Request for Authorization ○ Added: ▪ Discharge summary or recent progress note if member is being discharged from an inpatient setting (note: If	**Indications for Coverage** Before using this guideline, refer to the member specific benefit plan document and any federal or state mandates to determine if the plan has an exclusion for Private Duty Nursing. If the plan has the exclusion for Private Duty Nursing, then the services are not eligible for coverage. When Private Duty Nursing is a covered benefit, refer to the member specific benefit plan document for additional information regarding benefit coverage. ***Requirements for Coverage*** When benefits are available, Private Duty Nursing services are covered and considered Medically Necessary for members requiring individual and continuous Skilled Care when ordered by the member's primary care and/or treating physician as part of a Treatment Plan and when a member meets all of the following criteria: • Needs Skilled Care that exceeds the scope of Intermittent Care; and • Needs services that require the professional proficiency and skills of a licensed nurse (e.g., RN or LPN); and • Is unable to have their care tasks provided through, Intermittent Care, or self-directed care; and • Has a complex medical need and/or unstable medical condition that requires four (4) or more continuous hours of Skilled Care which can be safely provided outside an institution; and • Requires Skilled Care that is Medically Necessary for the member's disease, illness, or injury, as defined by the member's physician; and • Has family or other appropriate support that has the ability and availability to be trained to care for the member and assume a portion of the care. (Note: The intent of Private Duty Nursing services is to support not replace the caregiver); and • Face-to-face visit with the patient within 90 days prior to the start of care, or within 30 days after the start of care; and • Periodically reviewed Treatment Plan (no more frequently than every 90 days) updated by the treating physician; and

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Private Duty Nursing Services (continued)	Nov. 1, 2022	member is requesting Private Duty Nursing services for discharge from inpatient setting, subspecialist visit notes are not required) ▪ Delineated scope and duration of Private Duty Nursing hours being requested ▪ An assessment of the available support system must include but not limited to the following: – Availability of the member's primary caregiver; and – Ability of the member's primary caregiver to provide care; and – School attendance and availability of coverage for services by school district, if applicable; and – Primary caregiver's work schedules, as applicable ▪ Home care agency can safely deliver the required care at home ▪ Home environment is safe,	• The services are more cost-effective in the Home than in an alternate setting such as a hospital or a facility that provides Skilled Care (Note: Refer to the member specific benefit plan document for additional information regarding benefit coverage, as applicable) • Home care agency can safely deliver the required care at Home; and • Home environment is safe, accessible, and can be modified to accommodate the Home care plan **Coverage Limitations and Exclusions** • Requested services excluded in the benefit documents are not covered • Requested services beyond the plan benefits (hours or days) are not covered • Requested services defined as non-skilled or Custodial Care in the member specific benefit plan document (refer to the Coverage Determination Guideline titled Skilled Care and Custodial Care Services, the member specific benefit plan document, and/or any federal or state mandate requirements) such as but not limited to: ○ Members who are on continuous or bolus nasogastric (NG) or gastrostomy tube (GT) feedings and do not have other Skilled Care needs (Note: Transition from an inpatient setting to the Home may be considered Medically Necessary for these members when there is a need to train the member's family or caregiver to administer the NG or GT feedings); ○ Private Duty Nursing services become maintenance or Custodial Care and not Medically Necessary when any one of the following situations occur: ▪ Medical and nursing documentation shows that the member's condition is stable/predictable/controlled and that a licensed nurse is not required to monitor the condition; ▪ The Plan of Care does not require a licensed nurse to be in continuous attendance; ▪ The Plan of Care does not require hands-on nursing interventions (Note: Observation in case an intervention is required is not

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Private Duty Nursing Services (continued)	Nov. 1, 2022	accessible, and can be modified to accommodate the home care plan ▪ Verification of primary caregiver's employment schedule annually, as applicable ○ Removed: ▪ An assessment of the scope and duration of Private Duty Nursing services to be provided ○ Replaced: ▪ "Home Health Certification (CMS-485) which includes the Plan of Care signed by a physician (M.D. or D.O.)" with "Home Health Certification (CMS-485) which includes the Plan of Care signed by a physician (M.D. or D.O.) *or signed by an advanced practitioner (NP, CNS, or PA) in accordance with state law*" Renewal of Services *and* Transition of Services ○ Added: ▪ Home care agency can safely deliver the required care at home ▪ Home environment is safe, accessible, and can be	considered Skilled Care) ○ The following are examples of services that do not require the skills of a licensed nurse and therefore do not meet the medical necessity requirements for Private Duty Nursing services: ▪ Any duplication of care which is already provided by supply or infusion companies ▪ Care of an established colostomy/ileostomy ▪ Care of an established gastrostomy/jejunostomy/nasogastric tube (intermittent or continuous) feedings ▪ Care of an established indwelling bladder catheter (including emptying/changing containers and clamping tubing) ▪ Care of an established tracheostomy (including intermittent suctioning) ▪ Help with daily living activities, such as walking, grooming, bathing, dressing, getting in or out of bed, toileting, eating or preparing foods ▪ Institutional care, including room and board for rest cures, adult day care and convalescent care ▪ Respite care, adult (or child) day care, or convalescent care ▪ Routine administration of maintenance medications including insulin [this applies to oral (PO), subcutaneous (SQ) and intramuscular (IM) medications] ▪ Routine patient care such as changing dressings, periodic turning and positioning in bed, administering oral medications, or watching or protecting a member ▪ Services that can be provided safely and effectively by a non-clinically trained person are not skilled when a non-skilled caregiver is not available such as but not limited to: – Member must have one caregiver willing and able to accept responsibility for the member's care when the nurse is not available. If parent/caregiver cannot or will not accept responsibility for the care, Private Duty Nursing will not be authorized as this is deemed an unsafe environment

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Private Duty Nursing Services (continued)	Nov. 1, 2022	modified to accommodate the home care plan ▪ Verification of primary caregiver's employment schedule annually, as applicable ○ Replaced: ▪ "Home Health Certification (CMS-485) which includes the Plan of Care signed by a physician (M.D. or D.O.)" with "Home Health Certification (CMS-485) which includes the Plan of Care signed by a physician (M.D. or D.O.) *or signed by an advanced practitioner (NP, CNS, or PA) in accordance with state law*"	– Placement of the nurse in the Home is for the convenience of the family caregiver, including solely to allow the member's family or caregiver to go to work or school – Primary caregiver is identified as available and able, but is not willing to provide care to the member – There is no person available to assume the role of caregiver ▪ Respite care and convenience care unless mandated (Note: Respite care relieves the caregiver of the need to provide services to the member) ▪ Services that involve payment of family members or non-professional caregivers for services performed for the member unless required by state contract **Documentation Requirements** ***Initial Request for Authorization*** Initial service requests of Private Duty Nursing services (first time member is requesting services with UnitedHealthcare) must be submitted with all of the following clinical documentation: • Home Health Certification (CMS-485) which includes the Plan of Care signed by a physician (M.D. or D.O.) or signed by an advanced practitioner (NP, CNS, or PA) in accordance with state law; and • A comprehensive assessment of the member's health status including documentation of the skilled need and medication administration record; and • Discharge summary or recent progress note if member is being discharged from an inpatient setting (Note: If member is requesting Private Duty Nursing services for discharge from inpatient setting, subspecialist visit notes are not required); and • Consultation notes if the member is receiving services from subspecialist; and • Delineated scope and duration of Private Duty Nursing hours being requested; and • An assessment of the available support system must include but not limited

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Private Duty Nursing Services (continued)	Nov. 1, 2022		to the following: ○ Availability of the member's primary caregiver; and ○ Ability of the member's primary caregiver to provide care; and ○ School attendance and availability of coverage for services by school district, if applicable; and ○ Primary caregiver's work schedules, as applicable • Home care agency can safely deliver the required care at Home; and • Home environment is safe, accessible, and can be modified to accommodate the Home care plan; and • Verification of primary caregiver's employment schedule annually, as applicable Additional documentation clarifying clinical status (such as well child check and/or specialist visit notes) may be requested if clinical documentation provided does not support the hours required. ***Renewal of Services*** Requests for renewal of Private Duty Nursing services (any request subsequent to the initial request with UnitedHealthcare) will require submission of all of the following specific clinical documentation to support Medical Necessity: • Home Health Certification (CMS-485) which includes the Plan of Care signed by a physician (M.D. or D.O.) or signed by an advanced practitioner (NP, CNS, or PA) in accordance with state law; and • Nurses' notes, logs and daily care flow sheets, as applicable; and • Home care agency can safely deliver the required care at Home; and • Home environment is safe, accessible, and can be modified to accommodate the Home care plan; and • Verification of primary caregiver's employment schedule annually, as applicable ***Transition of Services*** If a member is transitioning from another health plan and is already receiving Private Duty Nursing services, then all of the following documentation must be

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Private Duty Nursing Services (continued)	Nov. 1, 2022		submitted before the end of the required continuity of care period: • Home Health Certification (CMS-485) which includes the Plan of Care signed by a physician (M.D. or D.O.) or signed by an advanced practitioner (NP, CNS, or PA) in accordance with state law; and • Nurses' notes, logs and daily care flow sheets, as applicable; and • Home care agency can safely deliver the required care at Home; and • Home environment is safe, accessible, and can be modified to accommodate the Home care plan; and • Verification of primary caregiver's employment schedule annually, as applicable

General Information

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

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

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

Policy Update Classifications

New

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

Updated

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

Revised

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

Replaced

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

Retired

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

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