UnitedHealthcare®

April 2018

medical policy update bulletin

Medical Policy, Medical Benefit Drug Policy & Coverage Determination Guideline Updates

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, Utilization Review Guideline, and Quality of Care Guideline updates.*

*Where information in this bulletin conflicts with applicable state and/or federal law, UnitedHealthcare follows such applicable federal and/or state law.

Medical Policy, Medical Benefit Drug Policy & Coverage Determination Guideline Updates

Overview

This bulletin provides complete details on UnitedHealthcare Medical Policy, Medical Benefit Drug Policy, Coverage Determination Guideline (CDG), Utilization Review Guideline (URG), and/or Quality of Care Guideline (QOCG) updates. The inclusion of a health service (e.g., test, drug, device or procedure) in this bulletin indicates only that UnitedHealthcare has recently adopted 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. In the event of an inconsistency or conflict between the information provided in this bulletin and the posted policy, the provisions of the posted policy will prevail. 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.

The complete library of UnitedHealthcare Medical Policies, Medical Benefit Drug Policies, CDGs, URGs, and QOCGs is available at **UHCprovider.com** > *Menu > Policies and Protocols > Commercial Policies > Medical & Drug Policies and Coverage Determination Guidelines.*

Tips for using the Medical Policy Update Bulletin:

- From the table of contents, click the policy title to be directed to the corresponding policy update summary.
- From the policy updates table, click the policy title to view a complete copy of a new, updated, or revised policy.

Policy Update Classifications

New

New clinical coverage criteria and/or documentation review requirements 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 or documentation review requirements; 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 and/or documentation review requirements

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

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.

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REVISED

Medical Policy Updates

Policy Title	Effective Date	Summary of Changes
UPDATED		
Chelation Therapy for Non-Overload Conditions	Apr. 1, 2018	• Updated coverage rationale; replaced language indicating: ○ "[The listed service] is proven *and* medically necessary" with "[the listed service] is proven *and/or* medically necessary" ○ "[The listed services] are unproven *and* not medically necessary" with "[the listed services] are unproven *and/or* not medically necessary" • Updated supporting information to reflect the most current description of services, clinical evidence, and references
Cochlear Implants	May 1, 2018	• Replaced references to "patient" with "individual" • Updated benefit considerations: ○ Replaced reference to "Covered Health Service" with "Covered Health *Care* Service" ○ Replaced language indicating "cochlear implant monitoring (remapping and reprogramming of implant) and rehabilitation following the cochlear implant surgery is usually billed as aural rehabilitation and is *not covered as a speech therapy benefit*" with "cochlear implant monitoring (remapping and reprogramming of implant) and rehabilitation following the cochlear implant surgery is usually billed as aural rehabilitation and is *covered as an outpatient rehabilitation therapy benefit*" • Updated coverage rationale; replaced language indicating: ○ "[The listed service] is proven *and* medically necessary" with "[the listed service] is proven *and/or* medically necessary" ○ "[The listed service] is unproven *and* not medically necessary" with "[the listed service] is unproven *and/or* not medically necessary" ○ "There is insufficient high quality evidence in the published clinical literature demonstrating the *safety and* efficacy of cochlear hybrid implants in the management of individuals with severe hearing loss" with "there is insufficient high quality evidence in the published clinical literature demonstrating the efficacy of cochlear hybrid implants in the management of individuals with severe hearing loss" • Updated list of applicable HCPCS codes: ○ Added V5273 ○ Removed L8621, L8622, L8623, L8624, and L8629 • Updated supporting information to reflect the most current clinical evidence, CMS information, and references
Computerized Dynamic Posturography	Apr. 1, 2018	• Updated coverage rationale; replaced language indicating "[the listed service] is unproven *and* not medically necessary" with "[the listed service] is unproven *and/or* not medically necessary" • Updated supporting information to reflect the most current clinical evidence, CMS information, and references
Deep Brain and Cortical Stimulation	Apr. 1, 2018	• Updated coverage rationale: ○ Replaced references to: ▪ "Patients" with "individuals" ▪ "*Patient* population" with "population" or "*study* population" ▪ "*Patient* selection criteria" with "selection criteria"

Medical Policy Updates

Policy Title	Effective Date	Summary of Changes
UPDATED		
Deep Brain and Cortical Stimulation *(continued)*	Apr. 1, 2018	○ Replaced language indicating: ▪ "[The listed services] are proven *and* medically necessary" with "[the listed services] are proven *and/or* medically necessary" ▪ "[The listed services] are unproven *and* not medically necessary" with "[the listed services] are unproven *and/or* not medically necessary" ○ Removed reference to specific directional deep brain stimulation device/product name (Infinity™ DBS System) ○ Added reference link to the *U.S. Food and Drug Administration (FDA)* section of the policy for information regarding directional deep brain stimulation devices • Updated supporting information to reflect the most current clinical evidence, FDA information, and CMS information
Embolization of the Ovarian and Iliac Veins for Pelvic Congestion Syndrome	Apr. 1, 2018	• Replaced language indicating "[the listed service] is unproven *and* not medically necessary" with "[the listed service] is unproven *and/or* not medically necessary" • Updated supporting information to reflect the most current clinical evidence and references
Infertility Diagnosis and Treatment	Jun. 1, 2018	• Added definition of: ○ Preimplantation Genetic Diagnosis (PGD) ○ Preimplantation Genetic Screening (PGS) • Updated supporting information to reflect the most current references
Thermography	Apr. 1, 2018	• Updated coverage rationale; replaced language indicating "[the listed service] is unproven *and* not medically necessary" with "[the listed service] is unproven *and/or* not medically necessary" • Updated supporting information to reflect the most current clinical evidence, FDA information, and references

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			
Chromosome Microarray Testing (Non-Oncology Conditions)	Jun. 1, 2018	• Changed policy title; previously titled *Chromosome Microarray Testing* • Updated list of related policies: ○ Added reference link to Medical Policy titled *Molecular Oncology Testing for Cancer Diagnosis, Prognosis, and Treatment*	**Genome-wide comparative genomic hybridization microarray testing or single nucleotide polymorphism (SNP) chromosomal microarray analysis is proven and/or medically necessary for evaluating an embryo/fetus in the following cases**: • Women undergoing invasive prenatal testing (i.e., amniocentesis, chorionic villus sampling or fetal tissue sampling) • Intrauterine Fetal Demise or Stillbirth **Genome-wide comparative genomic hybridization microarray testing**

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			
Chromosome Microarray Testing (Non-Oncology Conditions) *(continued)*	Jun. 1, 2018	*Decisions* ○ Removed reference link to Medical Policy titled *Gene Expression Tests for Cardiac Indications* • Revised coverage rationale: ○ Replaced reference to "patients" with "individuals" ○ Replaced language indicating: ▪ "[The listed services] are proven *and* medically necessary" with "[the listed services] are proven *and/or* medically necessary" ▪ "Genome-wide comparative genomic hybridization microarray testing *and* single nucleotide polymorphism (SNP) chromosomal microarray analysis are unproven *and* not medically necessary for all other *patient* populations and conditions [not listed as proven and/or medically necessary]" with "genome-wide comparative genomic hybridization microarray testing *or* SNP chromosomal microarray analysis are unproven *and/or* not medically necessary for all other populations and	**or SNP chromosomal microarray analysis is proven and/or medically necessary for evaluating individuals with one or more of the following**: • Multiple anomalies not specific to a well-delineated genetic syndrome and cannot be identified by a clinical evaluation alone • Non-syndromic Developmental Delay/Intellectual Disability • Autism spectrum disorder **Genome-wide comparative genomic hybridization microarray testing or SNP chromosomal microarray analysis are unproven and/or not medically necessary for all other populations and conditions including but not limited to the following:** • For evaluating an embryo/fetus in the following cases: ○ Preimplantation Genetic Diagnosis (PGD) in embryos ○ Preimplantation Genetic Screening (PGS) in embryos • Epilepsy There is insufficient evidence in the clinical literature demonstrating that genome-wide comparative genomic hybridization microarray testing or SNP chromosomal microarray analysis has a role in clinical decision-making or has a beneficial effect on health outcomes for other indications such as PGD in embryos, PGS in embryos, or epilepsy. Further studies are needed to determine the analytic validity, clinical validity, and clinical utility of this test for indications other than those listed above as proven. **Note**: Genome-wide comparative genomic hybridization microarray testing or SNP chromosomal microarray analysis for the evaluation of cancer is addressed in the Medical Policy for Molecular Oncology Testing for Cancer Diagnosis Prognosis, and Treatment Decisions. **Genetic Counseling** Genetic counseling is strongly recommended prior to this test in order to inform persons being tested about the advantages and limitations of the test as applied to a unique person.

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			
Chromosome Microarray Testing (Non-Oncology Conditions) *(continued)*	Jun. 1, 2018	conditions [not listed as proven and/or medically necessary]" ○ Updated list of populations and conditions for which genome-wide comparative genomic hybridization microarray testing or SNP chromosomal microarray analysis is unproven and/or not medically necessary: ▪ Added epilepsy ▪ Removed diagnosis, management, and prognosis of cancer ▪ Replaced "preimplantation genetic diagnosis or screening in embryos" with "Preimplantation Genetic Diagnosis (PGD) and Preimplantation Genetic Screening (PGS) in embryos" ○ Modified language pertaining to clinical evidence/study findings to indicate there is insufficient evidence in the clinical literature demonstrating that genome-wide comparative genomic hybridization microarray testing or SNP chromosomal microarray analysis has a role in clinical decision-making or has a beneficial effect on health outcomes for other indications such as PGD in embryos, PGS in	

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			
Chromosome Microarray Testing (Non-Oncology Conditions) *(continued)*	Jun. 1, 2018	embryos, or epilepsy ○ Added language to indicate genome-wide comparative genomic hybridization microarray testing or SNP chromosomal microarray analysis for the evaluation of cancer is addressed in the Medical Policy titled *Molecular Oncology Testing for Cancer Diagnosis Prognosis, and Treatment Decisions* • Added definition of: ○ Preimplantation Genetic Diagnosis (PGD) ○ Preimplantation Genetic Screening (PGS) ○ Prenatal Diagnosis • Updated list of applicable CPT codes: ○ Added 81479 ○ Removed 0004M • Reformatted list of applicable ICD-10 diagnosis codes; transferred content to embedded Excel file format • Updated supporting information to reflect the most current description of services, clinical evidence, and references	
Cognitive Rehabilitation	May 1, 2018	• Revised coverage rationale: ○ Replaced language indicating: ▪ "Cognitive rehabilitation is proven *and* medically necessary *for the treatment of* traumatic	**Cognitive rehabilitation (CR) is proven and/or medically necessary when treating individuals following a traumatic brain injury (TBI) or cerebral vascular accident.** The treatment regimen usually includes one of the following modalities: • Specific interventions for functional communication deficits, including pragmatic conversational skills, or • Compensatory memory strategy training.

Medical Policy Updates

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			
Cognitive Rehabilitation *(continued)*	May 1, 2018	brain injury (TBI) *and brain injury due to stroke, aneurysm, anoxia, encephalitis, brain tumors, and brain toxins when the patient can actively participate in the program (e.g., is not comatose or a vegetative or minimally conscious state which precludes such active engagement)*" with "cognitive rehabilitation (CR) is proven *and/or* medically necessary *when treating individuals following* a traumatic brain injury (TBI) *or cerebral vascular accident*" ▪ "Cognitive rehabilitation is unproven *and* not medically necessary for *the treatment of* cerebral palsy, Down syndrome, Alzheimer's disease, attention deficit hyperactivity disorder, developmental disorders such as autism, schizophrenia and Parkinson's disease" with "cognitive rehabilitation is unproven *and/or* not medically necessary for *treating* cerebral palsy, Down syndrome, Alzheimer's disease	**Cognitive rehabilitation is unproven and/or not medically necessary for treating cerebral palsy, Down syndrome, Alzheimer's disease (AD), attention deficit hyperactivity disorder (ADHD), developmental disorders such as autism, schizophrenia and Parkinson's disease**. Evidence in the published, peer-reviewed, medical literature to support the use of CR for these conditions is limited and conflicting. Available studies also contain design flaws including small study samples, lack of comparison groups and lack of long-term follow-up. **Coma stimulation is unproven and/or not medically necessary when treating individuals who are comatose or in a Vegetative or Minimally Conscious State who have sustained a brain injury.** There is limited evidence to conclude that coma stimulation will improve health outcomes. The overall methodological quality of available studies was poor and differed widely in terms of outcomes measures and study design.

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			
Cognitive Rehabilitation *(continued)*	May 1, 2018	(AD), attention deficit hyperactivity disorder (ADHD), developmental disorders such as autism, schizophrenia and Parkinson's disease" ▪ "Coma stimulation is unproven *and* not medically necessary *for the treatment of* comatose *patients* or *patients* in a Vegetative or Minimally Conscious State who have sustained a brain injury *due to limited evidence with overall poor quality in methodology and design, and diversity in reporting outcome measures*" with "coma stimulation is unproven *and/or* not medically necessary *when treating individuals who are* comatose or in a Vegetative or Minimally Conscious State who have sustained a brain injury" ○ Added language pertaining to clinical evidence/study findings to indicate there is limited evidence to conclude that coma stimulation will improve health outcomes; the overall methodological quality of available studies was poor and differed widely	

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REVISED			
Cognitive Rehabilitation *(continued)*	May 1, 2018	in terms of outcomes measures and study design • Updated supporting information to reflect the most current clinical evidence, CMS information, and references	
Electrical Stimulation for the Treatment of Pain and Muscle Rehabilitation	May 1, 2018	• Replaced references to "patients" with "individuals" • Revised coverage rationale; replaced language indicating: ○ "[The listed services] are proven *and* medically necessary" with "[the listed services] are proven *and/or* medically necessary" ○ "[The listed services] are unproven *and* not medically necessary" with "[the listed services] are unproven *and/or* not medically necessary" ○ "Peripheral subcutaneous field stimulation (PSFS) or peripheral nerve field stimulation (PNFS) is unproven *and* not medically necessary for *treating pain*" with "peripheral subcutaneous field stimulation (PSFS) or peripheral nerve field stimulation (PNFS) is unproven *and/or* not medically necessary for *all indications, including but not limited to pain and opioid management*" ○ "Evidence for the	**When used for walking, functional electrical stimulation (FES), a form of neuromuscular electrical stimulation (NMES), is proven and/or medically necessary when used as one component of a comprehensive rehabilitation program in persons with paralyzed lower limbs due to spinal cord injury (SCI) with all of the following characteristics**: • Intact lower motor units (L1 and below) (both muscle and peripheral nerves) • Muscle and joint stability for weight bearing at upper and lower extremities that can demonstrate balance and control to maintain an upright support posture independently; • Demonstrate brisk muscle contraction to NMES and have sensory perception of electrical stimulation (ES) sufficient for muscle contraction; • Possess high motivation, commitment and cognitive ability to use such devices for walking; • Able to transfer independently and demonstrate independent standing tolerance for at least 3 minutes; • Demonstrate hand and finger function to manipulate controls; • Post recovery from SCI and restorative surgery of at least 6-months; • No hip and knee degenerative disease and no history of long bone fracture secondary to osteoporosis **FES is unproven and/or not medically necessary for treating ANY other indication not listed above as proven and medically necessary, including but not limited to**: • Disuse muscle atrophy in persons with SCI • Disuse muscle atrophy in persons with multiple sclerosis (MS) • Gait disorders (e.g., foot drop) of central neurologic origin, including but not limited to stroke or MS Further studies are needed to confirm that FES promotes bone remineralization and prevents or reverses muscle atrophy. Only a few studies

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			
Electrical Stimulation for the Treatment of Pain and Muscle Rehabilitation *(continued)*	May 1, 2018	effectiveness of PSFS or PNFS based on controlled studies is *lacking*; *randomized controlled trials (RCTs)* are needed to evaluate the efficacy of this treatment" with "evidence for the effectiveness of PSFS or PNFS based on controlled studies is *limited*; *additional studies* are needed to evaluate the efficacy of this treatment" • Updated supporting information to reflect the most current clinical evidence, FDA information, and references	have looked at FES as a modality of treatment of MS, and the results are limited and conflicting regarding whether FES improves treatment outcomes in MS when offered in addition to other rehabilitative treatment modalities. There is insufficient evidence in the peer reviewed literature that use of FES will improve health outcomes in individuals with gait disorders. Published studies have included small heterogeneous patient populations, short-term follow-ups, and various treatment protocols, outcome measures, and FES devices. **NMES is proven and/or medically necessary for treating the following indications**: • Disuse muscle atrophy if: ○ The nerve supply to the muscle is intact; and ○ The disuse muscle atrophy is not of neurological origin but originates from conditions such as casting, splinting or contractures. • To improve wrist and finger function and prevent or correct shoulder subluxation in persons with partial paralysis following stroke **NMES is unproven and/or not medically necessary for treating ANY other indication not listed above as proven and medically necessary**. There is insufficient evidence in the peer reviewed literature that use of ES will improve health outcomes for the treatment of multiple conditions other than those identified above as proven. Overall, studies in the form of randomized controlled trials (RCTs) and case series included small, heterogeneous patient populations and short-term follow-ups. Some systematic reviews have reported that no improvement was seen with NMES, outcomes were conflicting and/or in some cases, when improvement was noted, the effects did not last. Heterogeneity of treatment regimens and outcome measures make it difficult to establish that NMES resulted in meaningful clinical outcomes (e.g., decrease pain, functional improvement, improvement in quality of life (QOL) and ability to carry out activities of daily living (ADLs)) for these other conditions and indications. **Interferential therapy (IFT) is unproven and/or not medically necessary for treating the following indications**: • For the treatment of musculoskeletal disorders or injuries • For stimulating healing of nonsurgical soft tissue injuries • To facilitate the healing of bone fractures

Medical Policy Updates

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			
Electrical Stimulation for the Treatment of Pain and Muscle Rehabilitation *(continued)*	May 1, 2018		There is limited evidence from the available studies to conclude that IFT reduces the pain or promotes healing of bone fractures, musculoskeletal or nonsurgical soft tissue injuries. Although a few studies reported some improvement in pain or disability following IFT for these conditions, none of the double-blind, randomized, placebo-controlled studies reported a positive treatment effect of IFT for nonsurgical soft tissue injuries or bone fractures. **Pulsed electrical stimulation (PES) is unproven and/or not medically necessary for treating osteoarthritis (OA)**. There is insufficient evidence to conclude that PES provides health benefits to individuals with OA. RCTs are necessary to assess the durability of this procedure in comparison to other types of treatment. **Peripheral subcutaneous field stimulation (PSFS) or peripheral nerve field stimulation (PNFS) is unproven and/or not medically necessary for all indications, including but not limited to pain and opioid management**. Evidence for the effectiveness of PSFS or PNFS based on controlled studies is limited. Additional studies are needed to evaluate the efficacy of this treatment. **Microcurrent electrical nerve stimulation (MENS) therapy is unproven and/or not medically necessary**. There is insufficient evidence to conclude that MENS is safe and effective. Robust clinical trials are needed to evaluate this therapy in comparison to other types of treatment. **Percutaneous electrical nerve stimulation (PENS) or percutaneous neuromodulation therapy (PNT) is unproven and/or not medically necessary for treating pain.** There is limited evidence in the peer reviewed literature to support that PENS or PNT will improve health outcomes in individuals with pain. RCTs assessing larger patient groups and long-term follow up are needed to further clarify its role. **Dorsal root ganglion (DRG) stimulation is unproven and/or not medically necessary**. There is limited evidence in the peer reviewed literature to support that DRG stimulation will improve health outcomes in individuals with pain. RCTs

Medical Policy Updates

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			
Electrical Stimulation for the Treatment of Pain and Muscle Rehabilitation *(continued)*	May 1, 2018		assessing larger patient groups and long-term follow up are needed to further clarify its role.

Molecular Oncology Testing for Cancer Diagnosis, Prognosis, and Treatment Decisions	Apr. 1, 2018	**Notice of Revision**: The following summary of changes has been modified. Revisions to the previous policy update announcement are outlined in red below. Please take note of the additional updates to be implemented on **Apr. 1, 2018**.
		
		• Revised coverage rationale:
		  ○ Updated list of unproven/not medically necessary gene expression profiling assays for colorectal cancer (CRC) risk assessment or management; removed "fecal DNA testing, i.e., ColonSentry"
		  ○ Replaced language indicating:
		  ▪ "[The listed services] are proven *and* medically necessary" with "[the listed services] are proven *and/or* medically necessary"
		  ▪ "[The listed services] are unproven *and* not medically necessary" with "[the listed services] are unproven *and/or* not medically necessary"
			Refer to the policy for complete details on the coverage guidelines for Molecular Oncology Testing for Cancer Diagnosis, Prognosis, and Treatment Decisions.

Medical Policy Updates

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			
Molecular Oncology Testing for Cancer Diagnosis, Prognosis, and Treatment Decisions *(continued)*	Apr. 1, 2018	○ Replaced reference to "patient" with "individual" • Updated list of applicable CPT codes; added 0012M*, 0013M*, 81520, and 81521 *(*quarterly code edit)* • Updated supporting information to reflect the most current references	
Omnibus Codes	May 1, 2018	• Removed coverage guidelines for collagen cross-linking of cornea analysis (CPT code 0402T); this service no longer requires clinical review	Refer to the policy for complete details on the coverage guidelines for Omnibus Codes.

Policy Title	Effective Date	Summary of Changes
RETIRED		
Thermal Capsulorrhaphy/ Thermal Shrinkage Therapy	Apr. 1, 2018	• Policy retired; thermal shrinkage therapy of joint capsules, ligaments, and tendons no longer requires clinical review

Medical Benefit Drug Policy Updates

Policy Title	Effective Date	Coverage Rationale
NEW		
Ketamine	Apr. 1, 2018	**Ketamine is considered medically necessary and may be covered for:** I. Anesthesia for diagnostic and surgical procedures that do not require skeletal muscle relaxation II. The induction of anesthesia prior to administration of other anesthesia agents III. As supplemental anesthesia for low-potency agents, such as nitrous oxide **Ketamine is investigational, and therefore not proven or medically necessary for:** I. Psychiatric disorders (including, but not limited to depression, bipolar disorder, & posttraumatic stress disorder) II. Chronic pain (including but not limited to nonmalignant pain, Fibromyalgia, neuropathic pain, Complex Regional Pain Syndrome, Reflex Sympathetic Dystrophy) III. Migraine headaches
Trogarzo™ (Ibalizumab-Uiyk)	Apr. 1, 2018	**Trogarzo (ibalizumab-uiyk) is proven and/or medically necessary for the treatment of multi-drug resistant human immunodeficiency virus (HIV) in patients who meet ALL of the following criteria:** I. For **initial therapy**, **all** of the following: A. **Both** of the following: 1. Diagnosis of HIV-1 infection 2. Physician attestation that the patient has multi-drug resistant HIV-1 infection **and** B. Physician confirms that the patient has been prescribed an optimized backround antiretroviral regimen, containing at least one antiretroviral agent that demonstrates full viral sensitivity/susceptibility; **and** C. Ibalizumab initial and maintenance dosing is in accordance with the US Food and Drug Administration prescribing information: A single loading dose of 2,000mg intravenously (IV) followed by a maintenance dose of 800mg IV every two weeks thereafter; **and** D. Initial authorization is for no more than 6 months. II. For **continuation therapy**, **all** of the following: A. Patient has previously received treatment with ibalizumab; **and** B. Physician confirms that the patient has achieved a clinically significant viral response to ibalizumab therapy; **and** C. Physician confirms that the patient will continue to take an optimized backround antiretroviral regimen, in combination with ibalizumab; **and** D. Ibalizumab maintenance dosing is in accordance with the US Food and Drug Administration prescribing information; **and** E. Authorization is for no more than 12 months.

Medical Benefit Drug Policy Updates

Policy Title	Effective Date	Summary of Changes
UPDATED		
Clotting Factors and Coagulant Blood Products	Apr. 1, 2018	• Updated list of applicable HCPCS codes to reflect quarterly code edits; revised description for J7188 and J7205
Exondys 51™ (Eteplirsen)	Apr. 1, 2018	• Updated coverage rationale; reformatted/clarified coverage criterion addressing applicable diagnosis and treating physician
Infliximab (Remicade®, Inflectra™, Renflexis™)	Apr. 1, 2018	• Updated list of applicable HCPCS codes to reflect quarterly code edits: ○ Added Q5103 and Q5104 ○ Removed Q5102 and corresponding modifiers ZB (Pfizer) and ZC (Merck) • Updated supporting information to reflect the most current clinical evidence, CMS information, and references
Rituxan® (Rituximab)	Apr. 1, 2018	• Updated coverage rationale; added language to clarify: ○ This policy refers only to Rituxan (rituximab) injection for intravenous infusion ○ For Rituxan Hycela (rituximab/hyaluronidase human), refer to the Oncology Medication Clinical Coverage Policy • Updated supporting information to reflect the most current references ○ Replaced reference to "MCG™ Care Guidelines, *21st* edition, *2017*" with "MCG™ Care Guidelines, *22nd* edition, *2018*"
Simponi Aria® (Golimumab) Injection for Intravenous Infusion	Apr. 1, 2018	• Updated supporting information to reflect the most current clinical evidence and references; no change to coverage rationale or lists of applicable codes ○ Replaced reference to "MCG™ Ambulatory Care *20th* Edition" with "MCG™ Ambulatory Care *22nd* Edition"
Spinraza™ (Nusinersen)	Apr. 1, 2018	• Updated coverage rationale: ○ Reformatted/clarified coverage criterion addressing applicable diagnosis and treating physician ○ Replaced references to "Hammersmith Infant Neurological Exam (HINE)" with "Hammersmith Infant Neurological Exam *Part 2* (HINE-*2*)" • Updated supporting information to reflect the most current clinical evidence and references
Stelara® (Ustekinumab)	Apr. 1, 2018	• Updated supporting information to reflect the most current FDA information and references; no change to coverage rationale or lists of applicable codes
White Blood Cell Colony Stimulating Factors	Apr. 1, 2018	• Updated list of applicable HCPCS codes to reflect quarterly code edits; revised description for Q5101

Medical Benefit Drug Policy Updates

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			
17-Alpha-Hydroxyprogesterone Caproate (Makena™ and 17P)	Apr. 1, 2018	• Revised coverage rationale; added language to indicate: ○ This policy provides coverage information about the use of injectable (both intramuscular and subcutaneous) 17-alpha-hydroxyprogesterone caproate ○ Subcutaneous injection of 17P is proven and medically necessary for prevention of spontaneous preterm birth when the criteria listed in the policy are met ○ Subcutaneous injection of 17P is unproven and not medically necessary for: ▪ Prevention of spontaneous preterm birth with any of the following: - Short cervix with or without cerclage and no prior preterm birth - Current mutli-fetal pregnancy (twins or greater) - Previous medically indicated preterm birth ▪ Initiation of 17P after 26 weeks, 6 days of gestation ○ Oral and intravaginal formulations of progesterone should be obtained through the members' pharmacy	This policy provides coverage information about the use of injectable (both intramuscular and subcutaneous) 17-alpha-hydroxyprogesterone caproate, commonly called 17P, may also be referred to as 17-OHP, 17-OHPC, 17Pc, Makena™, 17-alpha hydroxyprogesterone, hydroxyprogesterone, hydroxy-progesterone, and hydroxy progesterone. Hereafter, it will be referred to as 17P. **Note:** Oral and intravaginal formulations of progesterone are **not** addressed in this policy and should be obtained through the members' pharmacy benefit. **Intramuscular and subcutaneous injection of 17P is proven and medically necessary for prevention of spontaneous preterm birth when all of the following criteria are met:** I. Current singleton pregnancy; **and** II. History of a prior spontaneous preterm birth of a singleton pregnancy; **and** III. Treatment is initiated between 16 weeks, 0 days of gestation and 26 weeks, 6 days of gestation; **and** IV. Administration is to continue weekly until week 37 (through 36 weeks, 6 days) of gestation or delivery, whichever occurs first. **Intramuscular and subcutanous injection of 17P is unproven and not medically necessary for:** I. Prevention of spontaneous preterm birth with **any** of the following: A. Short cervix with or without cerclage and no prior preterm birth. B. Current mutli-fetal pregnancy (twins or greater). C. Previous medically indicated preterm birth. II. Initiation of 17P after 26 weeks, 6 days of gestation. Although there are ongoing clinical trials to broaden the indications for the use of 17P, at this time uses as indicated above are considered unproven. ***Additional Information regarding compounded 17P:** The active ingredient in the compounded 17P and Makena is hydroxyprogesterone caproate. Both have castor oil as an inactive ingredient. The compounded version can be made with an alternate oil base in the event of patient hypersensitivity to castor oil. Makena has the additional inactive ingredients of benzyl benzoate (1ml and 5ml vials) and

Medical Benefit Drug Policy Updates

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			
17-Alpha-Hydroxyprogesterone Caproate (Makena™ and 17P) *(continued)*	Apr. 1, 2018	benefit • Updated supporting information to reflect the most current clinical evidence, CMS information, and references	benzyl alcohol (a preservative, in the 5ml vial only). Based on the active ingredient, compounded preservative-free 17P is considered clinically interchangeable with Makena. Compounding pharmacies must comply with United States Pharmacopeia (USP) Chapter 797, which sets standards for the compounding, transportation, and storage of compounded sterile products (CSP).[1] The Pharmacy Compounding Accreditation Board will verify that the pharmacy is adhering to these standards. *__Note__: The FDA has stated that approved drug products provide a greater assurance of safety and effectiveness than do compounded products. Please refer to the *U.S. Food and Drug Administration (FDA)* section of the policy for additional information.
Lemtrada (Alemtuzumab)	Apr. 1, 2018	• Revised coverage rationale: ○ Replaced language indicating: ▪ "Lemtrada (alemtuzumab) is proven and medically necessary for treatment of relapsing-*remitting* multiple sclerosis when all of the [listed] criteria are met" with "Lemtrada (alemtuzumab) is proven and medically necessary for treatment of relapsing *forms of* multiple sclerosis when all of the [listed] criteria are met" ▪ "Alemtuzumab is unproven for the treatment of [the listed conditions]" with "alemtuzumab is unproven *and not*	**Lemtrada (alemtuzumab) is proven and medically necessary for treatment of relapsing forms of multiple sclerosis when ALL of the following criteria are met**: I. Diagnosis of relapsing forms of multiple sclerosis (MS) (e.g., relapsing-remitting MS, secondary-progressive MS with relapses, progressive-relapsing MS with relapses); **and** II. **One** of the following: A. **Treatment-naïve to alemtuzumab:** 1. Patient has history of failure following a trial for at least 4 weeks **or** history of intolerance to at least **two** of the following: a. interferon β-1a (Avonex® or Rebif®) b. interferon β-1b (Betaseron® or Extavia®) c. glatiramer acetate (Copaxone® or Glatopa®) d. dimethyl fumarate (Tecfidera®) e. teriflunomide (Aubagio®) f. fingolimod (Gilenya®) g. peginterferon beta-1a (Plegridy™) h. natalizumab (Tysabri®) i. daclizumab (Zinbryta™) j. ocrelizumab (Ocrevus®) **and** 2. Patient has **not** been previously treated with alemtuzumab; **and** 3. Patient is **not** receiving alemtuzumab in combination with another disease modifying agent for multiple sclerosis (e.g.,

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Lemtrada (Alemtuzumab) *(continued)*	Apr. 1, 2018	*medically necessary* for the treatment of [the listed conditions]" ○ Updated coverage criteria for proven and medically necessary indications; replaced criterion requiring: ▪ "Diagnosis of relapsing-*remitting* multiple sclerosis (*RR*MS)" with "diagnosis of relapsing *forms of* multiple sclerosis (MS) *(e.g., relapsing-remitting MS, secondary-progressive MS with relapses, progressive-relapsing MS with relapses)*" ▪ "Patient has history of failure following a trial for at least 4 weeks or history of intolerance *or contraindication* to two of the [listed drug products]" with "patient has history of failure following a trial for at least 4 weeks or history of intolerance to *at least* two of the [listed drug products]" - Updated list of drugs products requiring history of trial and failure or intolerance; added reference to brand name "Glatopa®" for glatiramer acetate	interferon beta preparations, glatiramer acetate, natalizumab, fingolimod, teriflunomide, etc.); **and** 4. Initial dosing is administered: 12 mg intravenously daily for 5 consecutive days; **and** 5. Regimen is administered only once within 12 months. **or** B. **Treatment-experienced with alemtuzumab:** 1. Patient has previously received treatment with alemtuzumab; **and** 2. Patient is **not** receiving alemtuzumab in combination with another disease modifying agent for multiple sclerosis (e.g., interferon beta preparations, glatiramer acetate, natalizumab, fingolimod, teriflunomide, etc.); **and** 3. Retreatment dosing is administered: 12 mg intravenously daily for 3 consecutive days; **and** 4. Regimen is administered only once within 12 months. Coverage of Lemtrada is limited to up to two treatment courses (5 day initial and 3 day end course). Requests for additional doses/courses beyond two courses will not be approved. **Alemtuzumab is unproven and not medically necessary for the treatment of:** • Rheumatoid arthritis • Autoimmune neutropenia • Autoimmune hemolytic anemia • Pure red cell aplasia • Immune thrombocytopenic purpura • Evans syndrome • Autoimmune pancytopenia

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Lemtrada (Alemtuzumab) *(continued)*	Apr. 1, 2018	• Updated supporting information to reflect the most current clinical evidence, FDA information, and references	
Maximum Dosage	Apr. 1, 2018	• Revised coverage rationale: ○ Updated HCPCS code based maximum dosage information for: **Inflectra (infliximab-dyyb)** ▪ Added Q5013 ▪ Removed Q5102 **Renflexis (infliximab-abda)** ▪ Added Q5104 ▪ Removed Q5102 ○ Updated maximum allowed quantities for National Drug Code (NDC) billing for **Herceptin (trastuzumab)**; added: ***NCD 50242-0132-01*** ▪ How Supplied: 150 mg powder for reconstitution ▪ Maximum Allowed: 3 vials ***NCD 50242-0333-01*** ▪ How Supplied: 420 mg powder for reconstitution ▪ Maximum Allowed: 3 vials • Updated list of applicable HCPCS codes to reflect quarterly code edits: ○ Added Q5013 and Q5104 ○ Removed Q5102 • Updated list of applicable NDCs; added 50242-0132-01 and	This policy provides information about the maximum dosage per administration for certain medications administered by a medical professional. **Drug Products:** • bevacizumab (Avastin®) • eculizumab (Soliris®) • infliximab (Remicade®) • infliximab-dyyb (Inflectra™) • infliximab-abda (Renflexis™) • omalizumab (Xolair®) • pegfilgrastim (Neulasta®) • rituximab (Rituxan®) • trastuzumab (Herceptin®) • ustekinumab (Stelara®) • vedolizumab (Entyvio®) • zoledronic acid (zoledronic acid, Reclast® and Zometa®) Most medications have a maximum dosage based upon body surface area or patient weight or a set maximal dosage independent of patient body size, and 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 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 (119 kg) and body surface area (2.45 meters^2) in the U.S. (Fryar, 2012). 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 > 119 kg or body surface area > 2.45 meters^2.

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Maximum Dosage *(continued)*	Apr. 1, 2018	50242-0333-01 • Updated supporting information to reflect the most current references	**Maximum Allowed Quantities for National Drug Code (NDC) Billing:** The allowed quantities for NDC billing are calculated based upon both the maximum dosage information supplied within this policy as well as the process by which NDC claims are billed. The list in the policy may not be inclusive of all available NDCs for each drug product and is subject to change. Refer to the policy for complete details on Maximum Dosage guidelines.

Coverage Determination Guideline (CDG) Updates

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Infertility Services	Jun. 1, 2018	• Revised coverage rationale/benefit limitations and exclusions: ○ Updated list of services excluded from coverage **for plans that include benefits for Infertility**; added: ▪ Preimplantation Genetic Diagnosis (PGD) **unless** the member has a benefit for Infertility that includes the Assisted Reproductive Technologies, the criteria listed in the *Indications for Coverage* section of the policy has been met, and the procedure is being performed for the diagnosis of known genetic disorders only when the fetus is at risk for an inheritable genetic disorder - This would include, but is not limited to the following: • Autosomal dominant disorders; • Sex-linked (X or Y chromosome) disorders; • Autosomal recessive diseases for which very specific	**Indications for Coverage** Therapeutic (medical or surgical) procedures to correct a physical condition, which is the underlying cause of the Infertility, are a covered health service (e.g., for the treatment of a pelvic mass or pelvic pain, thyroid disease, pituitary lesions, etc.). Services for the treatment of Infertility when provided by or under the care or supervision of a Physician are limited to the following procedures: • Ovulation induction (or controlled ovarian stimulation); • Insemination procedures: Artificial Insemination (AI) and Intra Uterine Insemination (IUI); • Assisted Reproductive Technologies (ART). To be eligible for Benefits, you must meet all of the following: • You are a female under age 44. • You are not able to become pregnant after the following periods of time of regular, unprotected intercourse or Therapeutic Donor Insemination: ○ One year, if you are a female under age 35. ○ Six months, if you are a female age 35 or older. • You have Infertility not related to voluntary sterilization or to failed reversal of voluntary sterilization. ***Surrogate/Gestational Carrier*** A member with an Infertility benefit that is using a Surrogate/Gestational Carrier because of a known medical cause of Infertility (this does not include a member who has had a voluntary sterilization or a failed reversal of a sterilization procedure) will have coverage for the following services. These services will be paid per the member's coverage. • Female member's ovary stimulation and retrieval of eggs are covered when a member is using a Surrogate (host uterus). **Please note**: The implantation of eggs or oocytes or donor sperm into a host uterus is not covered even if the member has the Infertility benefit. • Male member retrieval of sperm. **When applying the Infertility benefit, consider the following**: • Female Infertility: Infertility caused by a problem that results in the inability to produce an egg, if an embryo is unable to travel to the womb, or there is a process that prevents use of the womb for reproduction. • Male Infertility: Infertility caused by problems due to inability to

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Infertility Services *(continued)*	Jun. 1, 2018	mutations in heterozygosity can lead to a phenotype; • Recessive disorders (e.g. Spinal Muscular Atrophy) where it is not atypical for an affected child to have inherited one of the deletions in a de novo fashion - Check the benefit documents and state mandates for coverage of Preimplantation Genetic Diagnosis (PGD); PGD may be considered a covered expense if the fetus is at risk for a genetic disorder ▪ Preimplantation Genetic Screening (PGS) ○ Updated list of services excluded from coverage **for all plans**: ▪ Added: - Fees for the use of a Gestational Carrier or Surrogate - Pregnancy services for a Gestational Carrier or Surrogate who is not a Covered Person	ejaculate or insufficient number or motility of sperm. Please check the member specific benefit plan document for inclusion or exclusion. Some states mandate benefit coverage for Infertility services. Please check state mandates. **Benefit Limitations and Exclusions** **When the member's plan includes benefits for Infertility, the following services are not covered**: • Assisted Reproductive Technologies, ovulation induction and insemination procedures are excluded from coverage **unless** the member has a benefit for Infertility **and** the criteria listed in the Indications for Coverage has been met. • Pre-implantation Genetic Diagnosis (PGD) **unless** the member has a benefit for Infertility that includes the Assisted Reproductive Technologies, the criteria listed in the Indications for Coverage has been met, and the procedure is being performed for the diagnosis of known genetic disorders only when the fetus is at risk for an inheritable genetic disorder. ○ This would include, but is not limited to the following: ▪ Autosomal dominant disorders; ▪ Sex-linked (X or Y chromosome) disorders; ▪ Autosomal recessive diseases for which very specific mutations in heterozygosity can lead to a phenotype; ▪ Recessive disorders (e.g. Spinal Muscular Atrophy) where it is not atypical for an affected child to have inherited one of the deletions in a de novo fashion. ○ Check the benefit documents and state mandates for coverage of Pre-implantation Genetic Diagnosis (PGD). PGD may be considered a covered expense if the fetus is at risk for a genetic disorder • Pre-implantation Genetic Screening (PGS) • Cryo-preservation and other forms of preservation of reproductive materials, e.g., sperm, oocytes (eggs), embryos or ovarian. • Long-term storage (greater than one year) of reproductive materials such as sperm, eggs, embryos, ovarian tissue and testicular tissue. • Preservation of reproductive materials prior to cancer treatments and elective preservation of reproductive materials are not covered. This

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Infertility Services *(continued)*	Jun. 1, 2018	▪ Replaced "donor eggs and donor sperm *for surrogate parenting*" with "*costs* of donor eggs and donor sperm" ○ Updated additional information; removed duplicative language pertaining to the use of a Surrogate/Gestational Carrier • Added definition of: ○ Preimplantation Genetic Diagnosis (PGD) ○ Preimplantation Genetic Screening (PGS) • Updated supporting information to reflect the most current references	includes all services related, including but not limited to drug therapy, retrieval, cryopreservation and storage. • Donor services for donor sperm, ovum or oocytes (eggs), or embryos. ○ Donor eggs - All aspects of a donor egg cycle including stimulation, retrieval, fertilization, embryo culture and embryo transfer (fresh or frozen) are excluded from coverage unless otherwise specified in the plan language. ○ Donor sperm - The cost of procurement and storage of donor sperm is excluded. However, the thawing and insemination are covered if the member has an Infertility benefit that allows for artificial donor insemination. • In-vitro fertilization that is not an Assisted Reproductive Technology for the treatment of Infertility. This would include but is not limited to elective fertility preservation, embryo accumulation/banking. • Any Infertility services or supplies beyond the benefit maximum (dollars or procedures). • Infertility treatment when the cause of the Infertility was a procedure that produces sterilization, e.g., vasectomy or tubal ligation. (Check the member specific benefit plan document). **When the member's plan does not include benefits for Infertility, the following services are not covered**: • All health care services and related expenses for infertility treatments, including Assisted Reproductive Technology, regardless of the reason for the treatment. • Storage and retrieval of all reproductive materials. Examples include eggs, sperm, testicular tissue and ovarian tissue. • In vitro fertilization regardless of the reason for treatment. **The following services are excluded on all plans (even when the plan provides benefits for Infertility)**: • Surrogate Parenting: Services and treatments for a Gestational Carrier of a pregnancy that is not our member and all related services including, but not limited to: ○ Fees for the use of a gestational carrier or surrogate. ○ Pregnancy services for a gestational carrier or surrogate who is not a Covered Person. • Costs of donor eggs and donor sperm. • Unproven tests or procedures for Infertility. Refer to the Medical Policy

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Infertility Services *(continued)*	Jun. 1, 2018		titled Infertility Diagnosis and Treatment. • Self-injectable drugs for Infertility. Refer to the exclusion for self-injectable drugs in the member specific benefit plan document. Refer to the pharmacy benefit administrator for self-injectable medication benefit information. ***Additional Information*** • As a standard, coverage is provided for maternity services (prenatal, delivery and postnatal pregnancy) for our members. If a female member is pregnant and functioning as a Surrogate, coverage is provided for maternity services. Coverage is not provided for maternity services for a Surrogate that is not a member (see Surrogate parenting exclusion above). • Advanced Reproductive Technology Services (IVF, GIFT, ZIFT, PROS, and TET) requested for reasons other than Infertility, must be reviewed in accordance with the member specific benefit plan document (case by case determination).