UnitedHealthcare®

Medical Policy Update Bulletin

Medical Policy, Drug Policy & Coverage Determination Guideline (CDG) Updates

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Medical Policy Updates

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Medical Policy, Drug Policy & CDG Updates

A summary of recently approved, revised and/or retired Medical Policies, Drug Policies and CDGs is provided below for your review. You may access new and/or revised Medical Policies, Drug Policies and CDGs, in their entirety, along with an overview or summary of changes, in the following table. The appearance of an item or procedure in this bulletin indicates only that UnitedHealthcare has recently adopted, revised or retired a Medical Policy, Drug Policy or CDG; it does not imply that UnitedHealthcare provides coverage for the items or procedures listed. In the event of an inconsistency or conflict between the information provided in this bulletin and the posted Medical Policy, Drug Policy or CDG, the provisions of the posted policy will prevail. Note that most UnitedHealthcare benefit plan documents exclude from benefit coverage health services identified as investigational or unproven. Physicians and other health care professionals may not seek or collect payment from a UnitedHealthcare member for services not covered by the applicable benefit plan, unless they first obtain 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.

Medical Policy, Drug Policy & CDG Status Classifications

- **New:** New clinical coverage criteria and/or documentation review requirements have been adopted for a service, procedure, test, drug or device
- **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 procedural codes and/or services previously outlined in the policy are no longer being managed or are considered to be proven and are therefore not excluded as unproven services, unless coverage guidelines or criteria are otherwise documented in another policy or CDG. Note: The absence of a policy does not automatically indicate or imply coverage. As always, coverage for a service or procedure 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.

July 2014

UnitedHealthcare®

Medical Policy Update Bulletin

Medical Policy, Drug Policy & Coverage Determination Guideline (CDG) Updates

In This Issue

Medical Policy Updates

UPDATED

Title	Effective Date	Summary of Changes	Coverage Rationale
Athletic Pubalgia Surgery	Aug. 1, 2014	• Reorganized policy content • Added benefit considerations language for *Essential Health Benefits for Individual and Small Group* plans to indicate: o For plan years beginning on or after January 1, 2014, the Affordable Care Act of 2010 (ACA) requires fully insured non-grandfathered individual and small group plans (inside and outside of Exchanges) to provide coverage for ten categories of Essential Health Benefits ("EHBs") o Large group plans (both self-funded and fully insured), and small group ASO plans, are not subject to the requirement to offer coverage for EHBs; however, if such plans choose to provide coverage for benefits which are deemed EHBs (such as maternity benefits), the ACA requires all dollar limits on those benefits to be removed on all Grandfathered and Non-Grandfathered plans o The determination of which benefits constitute EHBs is made on a state by state basis; as such, when using this guideline, it is important to refer to the enrollee's specific plan document to determine benefit coverage • Updated coverage rationale; added language to indicate the unproven services are "not medically necessary"	**Surgical repair for treating athletic pubalgia is unproven and not medically necessary.** Several studies have shown that groin pain and function are improved after surgical repair for athletic pubalgia. However, most of these studies were uncontrolled, used small sample sizes and did not provide comparisons of the surgical methods used to treat athletic pubalgia. Large prospective randomized studies of individuals with athletic pubalgia with more detailed patient outcome measurements are needed to determine optimal treatment.

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Title	Effective Date	Summary of Changes	Coverage Rationale
Continuous Glucose Monitoring and Insulin Delivery for Managing Diabetes	Jul. 1, 2014	• Updated list of applicable HCPCS codes to reflect quarterly code edits (effective 07/01/2014); added S1034 – S1037	**Insulin Delivery** **External insulin pumps that deliver insulin by continuous subcutaneous infusion are proven and medically necessary for treating patients with diabetes. Programmable disposable external insulin pumps are considered equivalent to standard insulin pumps.** For information regarding medical necessity review, when applicable, see MCG™ Care Guidelines, 18th edition, 2014, Insulin Infusion Pump ACG:A-0339 (AC). **Nonprogrammable transdermal insulin delivery systems are unproven and not medically necessary for treating patients with diabetes.** There is insufficient evidence in the clinical literature demonstrating the safety and efficacy of transdermal insulin delivery in the management of patients with diabetes. **Implantable insulin pumps are investigational, unproven and not medically necessary.** No implantable insulin pumps have received U.S. Food and Drug Administration (FDA) approval at this time. While some preliminary studies reported improved glycemic control and fewer episodes of hypoglycemia in carefully selected patients, complications such as catheter blockage and infection were observed. Larger, randomized controlled trials are needed to determine the long-term impact of implantable insulin pumps on diabetes management. **Insulin infuser ports are unproven and not medically necessary for insulin delivery in patients with diabetes.** There is insufficient evidence demonstrating that the use of insulin infuser ports results in improved glycemic control beyond what can be achieved by using standard insulin delivery methods. In addition, an increase in complications, such as infection at the port site, has been reported when using these devices. Further well-designed, large-scale

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Continuous Glucose Monitoring and Insulin Delivery for Managing Diabetes *(continued)*	Jul. 1, 2014		randomized controlled trials are needed to establish the safety and efficacy of this device. See the *Description of Services* section of the policy for further details on the various types of insulin delivery systems. **Continuous Glucose Monitors with or without Combined Insulin Pumps** **Long-term continuous glucose monitoring (greater than 72 hours), alone or in combination with an external insulin pump, is proven and medically necessary as a supplement to self-monitoring of blood glucose (SMBG) for patients with type 1 diabetes who meet EITHER of the following criteria AND have demonstrated adherence to a physician ordered diabetic treatment plan:** • Have been unable to achieve optimum glycemic control as defined by the most current version of the American Diabetes Association (ADA) *Standards of Medical Care in Diabetes*; or • Have experienced hypoglycemia unawareness and/or frequent episodes of hypoglycemia For information regarding medical necessity review, when applicable, see MCG™ Care Guidelines, 18th edition, 2014, Continuous Glucose Monitoring ACG:A-0126 (AC). **Long-term continuous glucose monitoring is unproven and not medically necessary for patients with type 2 diabetes or gestational diabetes.** There is insufficient evidence that the use of long-term continuous glucose monitoring leads to improvement of glycemic control in patients with type 2 or gestational diabetes. **Remote Glucose Monitoring** **Remote glucose monitoring is unproven and not medically necessary for managing patients with diabetes.**

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Title	Effective Date	Summary of Changes	Coverage Rationale
Continuous Glucose Monitoring and Insulin Delivery for Managing Diabetes *(continued)*	Jul. 1, 2014		There is insufficient evidence in the clinical literature to conclude that remote glucose monitoring demonstrates improvement in clinical outcomes. **Artificial Pancreas Device Systems (APDS)** **Devices classified by the U.S. Food and Drug Administration (FDA) as an artificial pancreas are unproven and not medically necessary.** Study results fail to provide conclusive evidence that artificial pancreas devices lead to improved health outcomes, such as improved glycemic control or delay in diabetes-related complications, in patients with diabetes. Larger, randomized controlled trials are needed to determine the long-term impact of these devices on diabetes management. **Additional Information** As part of the ongoing effort to improve diabetes care, the National Diabetes Education Program, the American Association of Clinical Endocrinology and others have recommended the term "A1c" be used for GHB or hemoglobin A1c (HbA1c) measurement in health care practice to avoid confusion.
Gastrointestinal Motility Disorders, Diagnosis and Treatment	Aug. 1, 2014	• Reorganized policy content • Added benefit considerations language for *Essential Health Benefits for Individual and Small Group* plans to indicate: o For plan years beginning on or after January 1, 2014, the Affordable Care Act of 2010 (ACA) requires fully insured non-grandfathered individual and small group plans (inside and outside of Exchanges) to provide coverage for ten categories of Essential Health Benefits ("EHBs") o Large group plans (both self-funded and fully insured), and small group ASO plans, are not subject to the requirement	**Gastric Electrical Stimulation Therapy** **Gastric electrical stimulation therapy is proven and medically necessary for refractory diabetic gastroparesis that has failed other therapies, the treatment of chronic, intractable (drug-refractory) nausea and vomiting secondary to gastroparesis of diabetic or idiopathic etiology when used according to U.S. Food and Drug Administration (FDA) labeled indications.** See the *U.S. Food and Drug Administration (FDA)* section of the policy for information regarding FDA labeling and Humanitarian Device Exemption (HDE) for gastric electrical stimulation. **Manometry and Rectal Sensation, Tone, and Compliance Test** **The following tests are proven for evaluating anorectal function:**

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Title	Effective Date	Summary of Changes	Coverage Rationale
Gastrointestinal Motility Disorders, Diagnosis and Treatment *(continued)*	Aug. 1, 2014	to offer coverage for EHBs; however, if such plans choose to provide coverage for benefits which are deemed EHBs (such as maternity benefits), the ACA requires all dollar limits on those benefits to be removed on all Grandfathered and Non-Grandfathered plans o The determination of which benefits constitute EHBs is made on a state by state basis; as such, when using this guideline, it is important to refer to the enrollee's specific plan document to determine benefit coverage • Updated coverage rationale: o Reformatted and relocated information pertaining to medical necessity review; added language to indicate if service is "medically necessary" or "not medically necessary" to applicable proven/unproven statement	• **Rectal sensation, tone, and compliance test** • **Anorectal manometry** **Colonic manometry is unproven and not medically necessary for evaluating colon motility.** There is insufficient clinical evidence of efficacy in the published peer-reviewed medical literature for the use of colon motility testing or colonic manometry. Patient selection criteria and the role of colonic manometry in the management of motility abnormalities such as refractory constipation must be better defined in statistically robust, well-designed clinical trials. **Defecography** **Defecography is proven and medically necessary for the evaluation of intractable constipation, and for patients with constipation who have one or more of the following conditions that are suspected to be the cause of impaired defecation:** • Pelvic floor dyssynergia (inappropriate contraction of the puborectalis muscle) or • Enterocele (e.g. after hysterectomy) or • Anterior rectocele **Defecography is unproven and not medically necessary for the routine evaluation of constipation for conditions other than those listed above**. Direct visualization is the preferred method of evaluating intractable constipation in the absence of the stated indications above. **MRI defecography is unproven and not medically necessary for the evaluation of constipation and anorectal or pelvic floor disorders.** There is insufficient clinical evidence of efficacy in the published peer-reviewed medical literature for the use of MRI defecography. The utility of this advanced imaging technology in the evaluation and management of refractory

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Gastrointestinal Motility Disorders, Diagnosis and Treatment *(continued)*	Aug. 1, 2014		constipation must be better defined in statistically robust, well-designed clinical trials. **Electrogastrography and Electroenterography** **Cutaneous, mucous, or serosal electrogastrography or electroenterography is unproven and not medically necessary for diagnosing intestinal or gastric disorders including gastroparesis**. There is insufficient evidence to conclude that electrogastrography or electroenterography can accurately diagnose gastroparesis and other gastric or intestinal disorders. There are no data to conclude that electrogastrography or electroenterography is beneficial for health outcomes in patients with gastric or intestinal disorders.
Home Traction Therapy	Aug. 1, 2014	• Reorganized policy content • Added benefit considerations language for *Essential Health Benefits for Individual and Small Group* plans to indicate: o For plan years beginning on or after January 1, 2014, the Affordable Care Act of 2010 (ACA) requires fully insured non-grandfathered individual and small group plans (inside and outside of Exchanges) to provide coverage for ten categories of Essential Health Benefits ("EHBs") o Large group plans (both self-funded and fully insured), and small group ASO plans, are not subject to the requirement to offer coverage for EHBs; however, if such plans choose to provide coverage for benefits which are deemed EHBs (such as maternity benefits), the ACA requires all dollar limits on those benefits to be	**Home traction therapy is unproven and not medically necessary for the treatment of low back and neck disorders with or without radiculopathy.** The majority of studies are office based with mixed results. The quality of peer reviewed studies for home traction are limited as well to conclude that it is effective in the management of neck or low back pain or that it improves health outcomes. The indications for clinical application, patient selection criteria, risks, and comparison to alternative technologies have not been established for home traction therapy.

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Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Home Traction Therapy *(continued)*	Aug. 1, 2014	removed on all Grandfathered and Non-Grandfathered plans o The determination of which benefits constitute EHBs is made on a state by state basis; as such, when using this guideline, it is important to refer to the enrollee's specific plan document to determine benefit coverage • Updated coverage rationale; added language to indicate the unproven services are "not medically necessary" • Updated supporting information to reflect the most current description of services, clinical evidence, FDA and CMS information, and references	
Human Immuno-deficiency Virus (HIV) Tropism Testing	Aug. 1, 2014	• Reorganized policy content • Added benefit considerations language for *Essential Health Benefits for Individual and Small Group* plans to indicate: o For plan years beginning on or after January 1, 2014, the Affordable Care Act of 2010 (ACA) requires fully insured non-grandfathered individual and small group plans (inside and outside of Exchanges) to provide coverage for ten categories of Essential Health Benefits ("EHBs") o Large group plans (both self-funded and fully insured), and small group ASO plans, are not subject to the requirement to offer coverage for EHBs; however, if such plans choose to provide coverage for benefits which are deemed EHBs (such as maternity benefits), the ACA	**Tropism testing in human immunodeficiency virus (HIV) patients prior to initiating treatment with CCR5 inhibitors (e.g., maraviroc) is proven and medically necessary.**

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Human Immuno-deficiency Virus (HIV) Tropism Testing *(continued)*	Aug. 1, 2014	requires all dollar limits on those benefits to be removed on all Grandfathered and Non-Grandfathered plans o The determination of which benefits constitute EHBs is made on a state by state basis; as such, when using this guideline, it is important to refer to the enrollee's specific plan document to determine benefit coverage • Updated coverage rationale; added language to indicate the proven service is "medically necessary" • Updated list of applicable CPT codes; removed 87903 and 87904 • Updated supporting information to reflect the most current description of services, clinical evidence, FDA and CMS information, and references	
Magnetoence-phalography and Magnetic Source Imaging for Specific Neurological Indications	Aug. 1, 2014	• Reorganized policy content • Added benefit considerations language for *Essential Health Benefits for Individual and Small Group* plans to indicate: o For plan years beginning on or after January 1, 2014, the Affordable Care Act of 2010 (ACA) requires fully insured non-grandfathered individual and small group plans (inside and outside of Exchanges) to provide coverage for ten categories of Essential Health Benefits ("EHBs") o Large group plans (both self-funded and fully insured), and small group ASO plans, are not subject to the requirement to offer coverage for EHBs; however, if such	**Magnetoencephalography and magnetic source imaging (MEG/MSI) are proven and medically necessary for the following:** • **Presurgical evaluation in patients with intractable focal epilepsy** • **Presurgical evaluation of brain tumors and vascular malformations** • **Presurgical planning for refractory epilepsy when other methods do not localize a seizure focus.** **Magnetoencephalography and magnetic source imaging (MEG/MSI) are unproven and not medically necessary for the evaluation of brain function in patients with trauma, stroke, learning disorders, or other neurologic disorders and psychiatric conditions such as schizophrenia**. There is insufficient evidence to conclude that the use of MEG/MSI improves

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Title	Effective Date	Summary of Changes	Coverage Rationale
Magnetoence-phalography and Magnetic Source Imaging for Specific Neurological Indications *(continued)*	Aug. 1, 2014	plans choose to provide coverage for benefits which are deemed EHBs (such as maternity benefits), the ACA requires all dollar limits on those benefits to be removed on all Grandfathered and Non-Grandfathered plans o The determination of which benefits constitute EHBs is made on a state by state basis; as such, when using this guideline, it is important to refer to the enrollee's specific plan document to determine benefit coverage • Updated coverage rationale: o Reformatted and relocated information pertaining to medical necessity review; added language to indicate if service is "medically necessary" or "not medically necessary" to applicable proven/unproven statement	health outcomes such as improved diagnostic accuracy and treatment planning for patients with trauma, stroke, learning disorders, or other neurologic disorders and psychiatric conditions. Further clinical trials demonstrating the clinical usefulness of this procedure are necessary before it can be considered proven to have a benefit on health outcomes for these conditions.
Motorized Spinal Traction	Aug. 1, 2014	• Reorganized policy content • Added benefit considerations language for *Essential Health Benefits for Individual and Small Group* plans to indicate: o For plan years beginning on or after January 1, 2014, the Affordable Care Act of 2010 (ACA) requires fully insured non-grandfathered individual and small group plans (inside and outside of Exchanges) to provide coverage for ten categories of Essential Health Benefits ("EHBs") o Large group plans (both self-funded and fully insured), and small group ASO plans, are not	**Motorized spinal traction such as VAX-D and the Decompression Reduction Stabilization (DRS) System are unproven and not medically necessary for the treatment of neck and low back disorders.** There is insufficient evidence from peer-reviewed published studies to conclude that spinal unloading devices are effective in the management of neck or low back pain or that they improve health outcomes. The indications for use, patient selection criteria, risks, and comparison to alternative technologies have not been established for motorized traction therapy.

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Motorized Spinal Traction *(continued)*	Aug. 1, 2014	subject to the requirement to offer coverage for EHBs; however, if such plans choose to provide coverage for benefits which are deemed EHBs (such as maternity benefits), the ACA requires all dollar limits on those benefits to be removed on all Grandfathered and Non-Grandfathered plans o The determination of which benefits constitute EHBs is made on a state by state basis; as such, when using this guideline, it is important to refer to the enrollee's specific plan document to determine benefit coverage • Updated coverage rationale; added language to indicate the unproven service is "not medically necessary" • Updated supporting information to reflect the most current description of services, clinical evidence, FDA and CMS information, and references	
Standing Systems	Aug. 1, 2014	• Reorganized policy content • Added reference link to policy titled *Durable Medical Equipment, Orthotics, Ostomy Supplies, Medical Supplies and Repairs/Replacements* • Added benefit considerations language for *Essential Health Benefits for Individual and Small Group* plans to indicate: o For plan years beginning on or after January 1, 2014, the Affordable Care Act of 2010 (ACA) requires fully insured non-grandfathered individual and small group plans (inside and outside of Exchanges) to	**Stationary, mobile and active standing systems are unproven and not medically necessary for the treatment of individuals with neuromuscular disorders.** Conclusive evidence of the beneficial effects of a standing program has not been documented. No guidelines exist concerning the frequency and duration of the sessions that are required to achieve the benefits of standing.

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Standing Systems *(continued)*	Aug. 1, 2014	provide coverage for ten categories of Essential Health Benefits ("EHBs") o Large group plans (both self-funded and fully insured), and small group ASO plans, are not subject to the requirement to offer coverage for EHBs; however, if such plans choose to provide coverage for benefits which are deemed EHBs (such as maternity benefits), the ACA requires all dollar limits on those benefits to be removed on all Grandfathered and Non-Grandfathered plans o The determination of which benefits constitute EHBs is made on a state by state basis; as such, when using this guideline, it is important to refer to the enrollee's specific plan document to determine benefit coverage • Updated coverage rationale; added language to indicate the unproven service is "not medically necessary" • Updated list of applicable HCPCS codes; added E2230 and E2301 • Updated supporting information to reflect the most current description of services, clinical evidence, FDA and CMS information, and references	
Umbilical Cord Blood Harvesting and Storage for Future Use	Aug. 1, 2014	• Reorganized policy content • Added benefit considerations language for *Essential Health Benefits for Individual and Small Group* plans to indicate: o For plan years beginning on or after January 1, 2014, the Affordable Care Act of 2010 (ACA)	**Collection and storage of umbilical cord blood for possible later use is unproven and not medically necessary for a person currently healthy but desiring to provide the opportunity for a hypothetical, future transplantation.** Published clinical evidence on the use of umbilical cord blood is limited to diagnosis-specific indications for persons

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Title	Effective Date	Summary of Changes	Coverage Rationale
Umbilical Cord Blood Harvesting and Storage for Future Use *(continued)*	Aug. 1, 2014	requires fully insured non-grandfathered individual and small group plans (inside and outside of Exchanges) to provide coverage for ten categories of Essential Health Benefits ("EHBs") o Large group plans (both self-funded and fully insured), and small group ASO plans, are not subject to the requirement to offer coverage for EHBs; however, if such plans choose to provide coverage for benefits which are deemed EHBs (such as maternity benefits), the ACA requires all dollar limits on those benefits to be removed on all Grandfathered and Non-Grandfathered plans o The determination of which benefits constitute EHBs is made on a state by state basis; as such, when using this guideline, it is important to refer to the enrollee's specific plan document to determine benefit coverage • Updated coverage rationale; added language to indicate the unproven service is "not medically necessary" • Updated supporting information to reflect the most current FDA and CMS information and references	who would otherwise be eligible for human leukocyte antigen (HLA)-compatible allogeneic bone marrow or stem cell transplants. Current available clinical evidence does not support the hypothesis that storage for hypothetical future use improves health outcomes. For additional information and coverage of umbilical cord blood stem cell transplantation please refer to the UnitedHealth Group Transplant Review Guidelines.
Vagus Nerve Stimulation	Aug. 1, 2014	• Updated list of applicable CPT codes; removed 64569	**Vagus nerve stimulation (VNS) is proven for treating epilepsy in persons without a history of left or bilateral cervical vagotomy.** The U.S. Food and Drug Administration (FDA) identifies a history of left or bilateral cervical vagotomy as a contraindication to vagus nerve stimulation.

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Title	Effective Date	Summary of Changes	Coverage Rationale
Vagus Nerve Stimulation *(continued)*	Aug. 1, 2014		**Vagus nerve stimulation is unproven for treating all other indications, including the following:** • Alzheimer's disease • Anxiety disorder • Autism • Back and neck pain • Bipolar disorder • Bulimia • Cerebral palsy • Chronic pain syndrome • Cluster headaches • Depression • Fibromyalgia • Heart failure • Migraines • Morbid obesity • Narcolepsy • Obsessive-compulsive disorder • Paralysis agitans • Sleep disorders • Tourette's syndrome Available studies on the use of vagus nerve stimulation for treating severe, major depression or bipolar disorder refractory to medical therapy contain methodological flaws such as lack of control group, small sample size, potential bias, lack of randomization and blinding and lack of statistical power analysis. There is a substantial placebo effect associated with depression treatments and the lack of data from prospective randomized controlled or comparative clinical studies considerably limits the conclusions that can be drawn from the available evidence. Furthermore, preliminary analysis of a randomized controlled trial did not find a statistically significant difference between sham and active VNS. Definitive patient selection criteria for vagus nerve stimulation (VNS) in patients with treatment-resistant depression have not yet been established, and significant predictors of response have also not been identified. Early research has examined the use of vagus nerve stimulation for additional indications. However, because of limited

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Title	Effective Date	Summary of Changes	Coverage Rationale
Vagus Nerve Stimulation *(continued)*	Aug. 1, 2014		studies, small sample sizes and weak study designs, there is insufficient data to conclude that vagus nerve stimulation is safe and/or effective for treating these indications. **Information Pertaining to Medical Necessity Review (When Applicable)** Vagus nerve stimulation (VNS) is medically necessary for treating epilepsy in patients with medically refractory epileptic seizures who are not surgical candidates or have failed surgical intervention. It is an expectation that the physician have experience and expertise in the use of vagus nerve stimulation.

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Title	Effective Date	Summary of Changes	Coverage Rationale
Apheresis	Aug. 1, 2014	• Reorganized policy content • Added benefit considerations language for *Essential Health Benefits for Individual and Small Group* plans to indicate: o For plan years beginning on or after January 1, 2014, the Affordable Care Act of 2010 (ACA) requires fully insured non-grandfathered individual and small group plans (inside and outside of Exchanges) to provide coverage for ten categories of Essential Health Benefits ("EHBs") o Large group plans (both self-funded and fully insured), and small group ASO plans, are not subject to the requirement to offer coverage for EHBs; however, if such plans choose to provide coverage for benefits which are deemed EHBs (such as maternity benefits), the ACA requires all dollar limits on those benefits to be	**Therapeutic apheresis is proven and medically necessary for the following diagnoses:** • ABO incompatible heart transplantation in children less than 40 months of age (plasma exchange) • ABO incompatible hematopoietic stem cell and bone marrow transplant (plasma exchange) • ABO incompatible kidney transplantation (plasma exchange) • Acute inflammatory demyelinating polyneuropathy (Guillain-Barré syndrome) (plasma exchange) • ANCA-associated rapidly progressive glomerulonephritis (Wegener's Granulomatosis) (plasma exchange) • Anti-glomerular basement membrane disease (Goodpasture's syndrome) (plasma exchange) • Babesiosis (RBC exchange) • Cardiac allograft rejection or prophylaxis of cardiac transplant rejection (photopheresis) • Chronic inflammatory demyelinating polyneuropathy (plasma exchange) • Cryoglobulinemia (plasma exchange) • Cutaneous T-cell lymphoma;

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Title	Effective Date	Summary of Changes	Coverage Rationale
Apheresis *(continued)*	Aug. 1, 2014	removed on all Grandfathered and Non-Grandfathered plans o The determination of which benefits constitute EHBs is made on a state by state basis; as such, when using this guideline, it is important to refer to the enrollee's specific plan document to determine benefit coverage • Updated coverage rationale: o Reformatted and relocated information pertaining to medical necessity review; added language to indicate if service is "medically necessary" or "not medically necessary" to applicable proven/unproven statement	mycosis fungoides; Se´zary syndrome, erythrodermic (photopheresis) • Heterozygous or homozygous familial hypercholesterolemia (plasma exchange or selective adsorption) • Focal segmental glomerulosclerosis, recurrent (plasma exchange) • Graft-versus-host disease, skin, chronic (photopheresis) • Hyperleukocytosis, leukostasis (leukocytapheresis) • Hyperviscosity in monoclonal gammopathies, treatment of symptoms (plasma exchange) • IgG/IgA, or IgM type of paraproteinemic polyneuropathy (plasma exchange) • Lung allograft rejection (photopheresis) • Multiple sclerosis (relapsing form with steroid resistant exacerbations) (plasma exchange) • Myasthenia gravis (plasma exchange) • Neuromyelitis optica (Devic's syndrome) (plasma exchange) • Renal transplantation, antibody mediated rejection (plasma exchange) • Renal transplantation, desensitization, living or deceased donor recipients, positive crossmatch due to donor specific HLA antibody (plasma exchange) • Rheumatoid arthritis, refractory (immunoadsorption) • Sickle cell disease for one of the following: o Red blood cell exchange for treating acute stroke, acute chest syndrome, or multiorgan failure o Prophylaxis with red blood cell exchange for primary or secondary stroke prevention or for prevention of transfusional iron overload • Thrombotic thrombocytopenic purpura (plasma exchange) **Therapeutic apheresis including**

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Title	Effective Date	Summary of Changes	Coverage Rationale
Apheresis *(continued)*	Aug. 1, 2014		**plasma exchange, plasmapheresis, or photopheresis is unproven and not medically necessary for:** • ABO incompatible solid organ transplantation, liver perioperative • Acute disseminated encephalomyelitis • Acute liver failure • Age related macular degeneration • Amyloidosis, systemic • Amyotrophic lateral sclerosis • Aplastic anemia; pure red cell aplasia • Autoimmune hemolytic anemia: warm autoimmune hemolytic anemia; cold agglutinin disease • Burn shock resuscitation • Catastrophic antiphospholipid syndrome • Chronic focal encephalitis (Rasmussen's encephalitis) • Coagulation factor inhibitors • Cutaneous T-cell lymphoma; mycosis fungoides; Sézary syndrome, non-erythrodermic • Dermatomyositis or polymyositis • Dilated cardiomyopathy • Graft-versus-host disease, skin, acute • Graft-versus-host disease, non-skin, acute/chronic • Hereditary hemochromatosis • Hemolytic uremic syndrome • High density lipoprotein (HDL) delipidation and plasma reinfusion • Hyperleukocytosis, prophylaxis • Hypertriglyceridemic pancreatitis • Hyperviscosity in monoclonal gammopathies, prophylaxis for rituximab • IgG/IgA or IgM type of paraproteinemic polyneuropathy treated with immunoadsorption • Immune thrombocytopenic purpura • Immune complex rapidly progressive glomerulonephritis • Inclusion body myositis • Inflammatory bowel disease • Lambert-Eaton myasthenic syndrome • Malaria • Multiple myeloma type of

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Title	Effective Date	Summary of Changes	Coverage Rationale
Apheresis *(continued)*	Aug. 1, 2014		paraproteinemic polyneuropathy • Multiple sclerosis, chronic progressive or secondary progressive • Myeloma cast nephropathy • Nephrogenic systemic fibrosis • Overdose, venoms, and poisoning • Paraneoplastic neurologic syndromes • Pediatric autoimmune neuropsychiatric disorders associated with streptococcal infections (PANDAS) and Sydenham's chorea • Pemphigus vulgaris • Phytanic acid storage disease (Refsum's disease) • Polycythemia vera and erythrocytosis • POEMS (polyneuropathy, organomegaly, endocrinopathy, M protein, and skin changes) • Post transfusion purpura • Psoriasis • Red cell alloimmunization in pregnancy • Rheumatoid arthritis, refractory, treated with plasma exchange • Schizophrenia • Scleroderma (progressive systemic sclerosis) • Sepsis with multiorgan failure • Stiff-person syndrome • Systemic lupus erythematosus • Thrombocytosis • Thrombotic microangiopathy: drug-associated • Thrombotic microangiopathy: hematopoietic stem cell transplant-associated • Thyroid storm • Wilson's disease, fulminant There is insufficient evidence to conclude that apheresis, plasma exchange, plasmapheresis, immunoadsorption, or photopheresis is beneficial for health outcomes such as decreased morbidity and mortality rates in patients with disorders other than those listed as proven. **Apheresis is first-line therapy for the following conditions:** • Acute inflammatory demyelinating

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Title	Effective Date	Summary of Changes	Coverage Rationale
Apheresis *(continued)*	Aug. 1, 2014		polyneuropathy (Guillain-Barré syndrome) (plasma exchange) • ANCA-associated rapidly progressive glomerulonephritis (Wegener's Granulomatosis) (plasma exchange) • Anti-glomerular basement membrane disease (Goodpasture's syndrome) (plasma exchange) • Babesiosis (RBC exchange) • Cardiac allograft rejection prophylaxis (photopheresis) • Chronic inflammatory demyelinating polyneuropathy (plasma exchange) • Cryoglobulinemia (plasma exchange) • Cutaneous T-cell lymphoma; mycosis fungoides; Se´zary syndrome, erythrodermic (photopheresis) • Homozygous familial hypercholesterolemia (plasma exchange or selective adsorption) • Hyperleukocytosis, leukostasis (leukocytapheresis) • Hyperviscosity in monoclonal gammopathies, treatment of symptoms (plasma exchange) • IgG/IgA, or IgM type of paraproteinemic polyneuropathy (plasma exchange) • Myasthenia gravis (plasma exchange) • Renal transplantation, antibody mediated rejection (plasma exchange) • Renal transplantation, desensitization, living or deceased donor recipients, positive crossmatch due to donor specific HLA antibody (plasma exchange) • Sickle cell disease for one of the following: o Red blood cell exchange for treating acute stroke or multiorgan failure o Prophylaxis with red blood cell exchange for primary or secondary stroke prevention or for prevention of transfusional iron overload • Thrombotic thrombocytopenic

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Title	Effective Date	Summary of Changes	Coverage Rationale
Apheresis *(continued)*	Aug. 1, 2014		purpura (plasma exchange) **Apheresis is proven and medically necessary for persons who are refractory to or intolerant of standard therapy for the following conditions where apheresis is second-line therapy:** • ABO incompatible heart transplantation in children less than 40 months of age (plasma exchange) • ABO incompatible hematopoietic stem cell and bone marrow transplant (plasma exchange) • ABO incompatible kidney transplantation (plasma exchange) • Cardiac allograft rejection (photopheresis) • Focal segmental glomerulosclerosis, recurrent (plasma exchange) • Heterozygous familial hypercholesterolemia (plasma exchange or selective adsorption) • Graft-versus-host disease, skin, chronic (photopheresis) • Lung allograft rejection (photopheresis) • Multiple sclerosis (relapsing form with steroid resistant exacerbations) (plasma exchange) • Neuromyelitis optica (Devic's syndrome) (plasma exchange) • Rheumatoid arthritis, refractory (immunoadsorption) • Sickle cell disease, acute chest syndrome (red blood cell exchange)
Attended Polysomno-graphy for Evaluation of Sleep Disorders	Aug. 1, 2014	• Changed policy title; previously titled *Polysomnography and Portable Monitoring for Sleep Related Breathing Disorders* • Revised benefit considerations; removed content/language specific to ASO plan membership • Reorganized/reformatted and revised coverage rationale: o Removed content/language specific to unattended full-channel or limited channel portable monitoring/home	**I. Attended full-channel nocturnal polysomnography (NPSG)/laboratory sleep test (LST), performed in a healthcare facility is proven and medically necessary in patients with suspected OSA and one (1) or more of the following indications:** A. One (1) or more of the following documented co-morbid conditions that would degrade the accuracy of portable monitoring with a home sleep test (HST): 1. Significant chronic

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Title	Effective Date	Summary of Changes	Coverage Rationale
Attended Polysomnography for Evaluation of Sleep Disorders *(continued)*	Aug. 1, 2014	sleep test (HST) **Attended Full-Channel Nocturnal Polysomnography (NPSG)/Laboratory Sleep Test (LST)** o Combined guidelines for *patients previously diagnosed* and *patients not previously diagnosed* with obstructive sleep apnea (OSA); revised coverage statement to indicate attended full-channel nocturnal polysomnography (NPSG)/laboratory sleep test (LST), performed in a healthcare facility, is proven and medically necessary in patients with *suspected* OSA when the noted criteria is met o Revised list of proven/medically necessary indications: *Co-Morbid Conditions* ▪ Replaced reference to "co-morbid conditions" with "*documented* co-morbid conditions" ▪ Replaced reference to "neuromuscular disease/neurodegenerative disorder" with "*progressive* neuromuscular disease/neurodegenerative disorder" ▪ Replaced reference to "significant cardiac disease" with "*moderate to severe* cardiac disease" ▪ Replaced reference to "significant persistent cardiac arrhythmia" with "uncontrolled cardiac tachyarrhythmia or bradyarrhythmia" *Complex Sleep Disorders* ▪ Replaced reference to	pulmonary disease as defined by a forced expiratory volume (FEV1%pred) of <60 (Pelligrino, 2005) 2. Progressive neuromuscular disease/neurodegenerative disorder [examples include but are not limited to, Parkinson's disease, myotonic dystrophy, amyotrophic lateral sclerosis, multiple sclerosis with associated pulmonary disease, history of stroke with persistent neurological sequelae] 3. Moderate to severe cardiac disease [examples include but are not limited to, congestive heart failure (NYHA class III or IV), uncontrolled cardiac tachyarrhythmia or bradyarrhythmia, pulmonary hypertension] 4. Body mass index (BMI) >50 (DeMaria 2007, Blackstone 2009) 5. Obesity Hypoventilation Syndrome (OHS); **OR** B. One (1) or more of the following document complex sleep disorders: 1. Severe chronic periodic limb movement disorder (PLMD) (not leg movements associated with another disorder such as sleep disordered breathing) 2. Restless leg syndrome (RLS)/Ekbom that has not responded to treatment 3. Parasomnia with disruptive, violent or

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Title	Effective Date	Summary of Changes	Coverage Rationale
Attended Polysomnography for Evaluation of Sleep Disorders *(continued)*	Aug. 1, 2014	"sleep disorders" with "*complex* sleep disorders" ▪ Replaced "periodic limb movement disorder (PLMD)" with "*severe chronic* periodic limb movement disorder (PLMD) *(not leg movements associated with another disorder such as sleep disordered breathing)*" ▪ Added *"restless leg syndrome (RLS)/Ekbom that has not responded to treatment"* *Age Requirement* ▪ Changed age requirement from "child or adolescent ≤ 20 years of age" to "child or adolescent < 18 years of age" **Actigraphy** o Added language to indicate actigraphy is unproven/not medically necessary for evaluation of circadian rhythm disorders; the evidence regarding use of actigraphy for evaluation of circadian rhythm disorders is of low quality and therefore the clinical utility could not be established **Split Night Study with Positive Airway Pressure (PAP) Titration** o Changed applicable site of service from "a healthcare facility" to "an attended sleep laboratory" **Full Night Study with Positive Airway Pressure (PAP) Titration** o Changed applicable site	potentially injurious sleep behavior suspicious of rapid eye movement (REM) (RBD) disorder 4. Narcolepsy once other causes of excessive sleepiness have been ruled out 5. History of central sleep apnea; **OR** C. Patient is a child or adolescent (i.e. <18 years of age); **OR** D. Results of previous HST were either: 1. Indeterminate for suspected OSA or upper airway resistance syndrome; **or** 2. Technically inadequate after 2-3 nights; **or** 3. Patient lacks the mobility or dexterity to use HST equipment safely at home; **or** 4. Cognitive impairment such that patient is unable to perform a home sleep study **II. Attended full-channel nocturnal polysomnography (NPSG)/laboratory sleep test (LST), performed in a healthcare facility is unproven and not medically necessary for the evaluation of sleep disorders for any of the following:** A. Significant chronic lung disease in the absence of symptoms of sleep disorder B. Circadian rhythm disorders C. Positive airway pressure (CPAP or Bi-Level) evaluation in patients whose symptoms continue to resolve with CPAP or Bi-Level treatment D. Depression E. Insomnia F. Epileptic seizures in the

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Title	Effective Date	Summary of Changes	Coverage Rationale
Attended Polysomnography for Evaluation of Sleep Disorders *(continued)*	Aug. 1, 2014	of service from "a healthcare facility" to "an attended sleep laboratory" o Revised criteria pertaining to the feasibility of a split night study; replaced criterion indicating the continuous positive airway pressure (CPAP) titration portion of the original study "failed to effectively eliminate respiratory events" with "failed to effectively *minimize* respiratory events" **Repeat Testing** o Changed applicable site of service from "a healthcare facility" to "an attended sleep laboratory" • Revised definitions: o Added definition of: ▪ Obstructive Apnea ▪ Periodic Limb Movement (PLM) ▪ Periodic Limb Movement Arousal Index (PLMAI) ▪ Periodic Limb Movement Index (PLMI) o Updated definition of: ▪ Central Apnea ▪ Periodic Limb Movement Disorder (PLMD) • Updated list of applicable ICD-9 diagnosis codes; removed 89.17 • Updated list of applicable CPT codes; removed 95800, 95801 and 95806 • Updated list of applicable HCPCS codes; removed G0398, G0399 and G0400 • Updated supporting information to reflect the most current description of services, clinical evidence, FDA and CMS information, and references	absence of symptoms of sleep disorder There is insufficient published clinical evidence that evaluation of the above disorders with polysomnography (PSG) in the absence of symptoms of sleep disorder leads to better health outcomes. **III. Actigraphy is unproven and not medically necessary for evaluation of sleep related breathing disorders and circadian rhythm disorders.** A review of the evidence does not establish the effectiveness of actigraphy as a standalone tool for diagnosis of obstructive sleep apnea syndrome. In addition, definitive patient selection criteria for the use of actigraphy devices for diagnosis of sleep apnea have not been established. The evidence regarding use of the actigraphy for evaluation of circadian rhythm disorders is of low quality and therefore the clinical utility could not be established. **IV. Multiple sleep latency testing (MSLT) is proven and medically necessary for suspected narcolepsy.** For information regarding medical necessity review, when applicable, see MCG™ Care Guidelines, 18th edition, 2014, Multiple Sleep Latency Test (MSLT) and Maintenance of Wakefulness Test (MWT), A-0146 (AC). **V. Maintenance of wakefulness testing (MWT) is proven and medically necessary for assessment of individuals in whom the inability to remain awake constitutes a safety issue, or for patients with narcolepsy or idiopathic hypersomnia to assess response to treatment with**

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Title	Effective Date	Summary of Changes	Coverage Rationale
Attended Polysomno-graphy for Evaluation of Sleep Disorders *(continued)*	Aug. 1, 2014		**medications.** For information regarding medical necessity review, when applicable, see MCG™ Care Guidelines, 18th edition, 2014, Multiple Sleep Latency Test (MSLT) and Maintenance of Wakefulness Test (MWT), A-0146 (AC). **VI. Multiple sleep latency testing (MSLT) and the maintenance of wakefulness test (MWT) are unproven and not medically necessary for the evaluation and diagnosis of obstructive sleep apnea.** Available published evidence is insufficient to demonstrate improved management of obstructive sleep apnea through the use of MSLT. Published evidence is limited to poorly controlled studies for obstructed sleep apnea. **VII. A split night study with positive airway pressure (PAP) titration performed in an attended sleep laboratory is proven and medically necessary in patients who have met the criteria for attended full channel nocturnal polysomnography studies and if the diagnosis of OSA can be made within the first 2 hours of recorded sleep, and at least 3 hours of CPAP titration.** **VIII. A full night study with positive airway pressure (PAP) titration performed in an attended sleep laboratory is proven and medically necessary in patients who have met the criteria for attended full channel nocturnal polysomnography studies and with confirmed OSA, as determined by either of the following:** A. In patients where the split night was not feasible, as determined by:

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Title	Effective Date	Summary of Changes	Coverage Rationale
Attended Polysomno-graphy for Evaluation of Sleep Disorders *(continued)*	Aug. 1, 2014		1. AHI in the first two hours of testing was less than 20 per hour; **or** 2. The CPAP titration portion of the original study was insufficient; • Less than three hours of titration; **or** • Failure to effectively minimize respiratory events **OR** B. Follow-up titration in patients with persistent or new symptoms despite current CPAP treatment. **Repeat Testing** It may be necessary to perform repeat sleep studies. Where repeat testing is indicated, attended full-channel nocturnal polysomnography (NPSG)/laboratory sleep test (LST) performed in an attended sleep laboratory is proven and medically necessary for persons who meet criteria for attended (LST) above. Where unattended portable monitoring/HST are indicated, an auto-titrating continuous positive airway pressure (APAP) device is an option to determine a fixed CPAP pressure.
Cochlear Implants	Aug. 1, 2014	• Revised coverage rationale: o Changed coverage status for *cochlear hybrid implants for hearing loss* from "investigational" to "unproven and not medically necessary" • Updated supporting information to reflect the most current description of services, clinical evidence, FDA and CMS information, and references	**When used according to U.S. Food and Drug Administration (FDA) labeled indications, bilateral or unilateral cochlear implantation is proven and medically necessary for patients who meet all of the following criteria:** • Diagnosis of bilateral prelingual or postlingual moderate-to-profound sensorineural hearing impairment with limited benefit from appropriate hearing (or vibrotactile) aids; • Ability to follow or participate in a program of aural rehabilitation; • Freedom from middle ear infection, an accessible cochlear lumen that is structurally suited to implantation, and freedom from lesions in the auditory nerve and acoustic areas of

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Title	Effective Date	Summary of Changes	Coverage Rationale
Cochlear Implants *(continued)*	Aug. 1, 2014		the central nervous system; • No contraindications to surgery See the *U.S. Food and Drug Administration (FDA)* section of the policy for FDA indications for each cochlear implant device. Specific criteria vary with the device. **Cochlear hybrid implants are unproven and not medically necessary for hearing loss.** There is insufficient evidence in the clinical literature demonstrating the safety and efficacy of cochlear hybrid implants in the management of patients with severe hearing loss. Published evidence has shown that there is a potential risk of low frequency hearing loss as a result of cochlear hybrid implant surgery. Studies are needed to verify that benefits are likely to outweigh the risks of cochlear hybrid implantation and to determine which group of patients would benefit most from this device.
Infertility Diagnosis and Treatment	Aug. 1, 2014	• Revised coverage rationale: o Added language to indicate cryopreservation of immature oocytes (eggs) is unproven and not medically necessary o Added language to indicate if service is "medically necessary" or "not medically necessary" to existing proven/unproven statements • Updated list of applicable CPT codes to codes to reflect quarterly code edits (effective 07/01/2014): o Added 0357T o Reorganized code listings specific to cryopreservation	**Diagnostic Procedures** ***Females*** **The following tests or procedures are proven and medically necessary for diagnosing infertility in female patients:** • Antral follicle count • Clomiphene citrate challenge test • The following hormone level tests: o antimüllerian hormone (AMH) o estradiol o follicle-stimulating hormone (FSH) o luteinizing hormone (LH) o progesterone o prolactin o thyroid-stimulating hormone (TSH) • Hysterosalpingogram (HSG) • Diagnostic hysteroscopy • Diagnostic laparoscopy with or without chromotubation • Pelvic ultrasound (transabdominal or transvaginal) • Sonohysterogram or saline infusion ultrasound

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Title	Effective Date	Summary of Changes	Coverage Rationale
Infertility Diagnosis and Treatment *(continued)*	Aug. 1, 2014		**The following tests are unproven and not medically necessary for diagnosing infertility in female patients:** • Inhibin B • Uterine/endometrial receptivity testing (e.g., E-tegrity® and Endometrial Function Test® (EFT®)) There is insufficient evidence to permit conclusions regarding the use of these tests. More studies are needed to support improved outcomes (i.e., increased successful pregnancies with delivery of liveborn children) with use of these diagnostic tests. ***Males*** **The following tests or procedures are proven and medically necessary for diagnosing infertility in male patients:** • Antisperm antibodies • The following genetic screening tests: o cystic fibrosis gene mutations o karyotyping for chromosomal abnormalities o Y-chromosome microdeletions testing • The following hormone level tests: o LH o FSH o prolactin o testosterone (total and free) • Leukocyte count in semen • Post-ejaculatory urinalysis • Scrotal, testicular or transrectal ultrasound • Semen analysis • Testicular biopsy • Vasography **The following tests are unproven and not medically necessary for diagnosing infertility in male patients:** • Computer-assisted sperm analysis (CASA) • Hyaluronan binding assay (HBA) • Postcoital cervical mucus penetration test • Reactive oxygen species (ROS) test • Sperm acrosome reaction test • Sperm DNA integrity/fragmentation tests (e.g. sperm chromatin structure

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Title	Effective Date	Summary of Changes	Coverage Rationale
Infertility Diagnosis and Treatment *(continued)*	Aug. 1, 2014		assay (SCSA), single-cell gel electrophoresis assay (Comet), deoxynucleotidyl transferase-mediated dUTP nick end labeling assay (TUNEL), sperm chromatin dispersion (SCD) or Sperm DNA Decondensation™ Test (SDD)) • Sperm penetration assays There is insufficient evidence to permit conclusions regarding the use of these tests. More studies are needed to support improved outcomes (i.e., increased successful pregnancies with delivery of liveborn children) with use of these diagnostic tests. **Therapeutic Procedures** **The following procedures are proven and medically necessary for the treatment of infertility:** • Assisted reproductive technologies (e.g., in vitro fertilization (IVF), gamete intrafallopian transfer (GIFT) and elective single-embryo transfer (eSET)) • Ovulation induction or controlled ovarian stimulation • Insemination procedures • Assisted embryo hatching • Intracytoplasmic sperm injection (ICSI) for treating male factor infertility • Sperm retrieval techniques (e.g., microsurgical epididymal sperm aspiration (MESA), percutaneous epididymal sperm aspiration (PESA), testicular sperm extraction (TESE), testicular sperm aspiration (TESA) and electroejaculation) **The following procedures to correct underlying disorders are proven and medically necessary for the treatment of infertility:** • Lysis of adhesions • Drainage of ovarian cyst • Surgery (laparoscopic or open) for endometriosis • Surgery (laparoscopic or open) to repair diseased, damaged or blocked fallopian tubes (e.g., fimbrioplasty, salpingostomy, neosalpingostomy) • Transurethral resection of

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Title	Effective Date	Summary of Changes	Coverage Rationale
Infertility Diagnosis and Treatment *(continued)*	Aug. 1, 2014		ejaculatory ducts for treating ejaculatory duct obstruction • Varicocele repair • Wedge resection of ovary or ovarian drilling in women with polycystic ovary syndrome. (NOTE: Ovarian drilling is a measure of last resort due to the increased risk of pelvic adhesions.) **The following procedures are unproven and not medically necessary for treating infertility:** • Co-culture of embryos • EmbryoGlue® • In vitro maturation (IVM) of oocytes Studies describe different techniques of co-culture of embryos, but no standardized method of co-culturing has been defined. The use of co-cultures may improve blastocyst development but may not result in an improved pregnancy or delivery rate. There is inadequate published scientific data to permit conclusions regarding the use of EmbryoGlue. Although preliminary results with IVM are promising, studies to date show that implantation and pregnancy rates are significantly lower than those achieved with standard IVF. Further evidence from well-designed trials is needed to determine the long-term safety and efficacy of the procedure. **Cryopreservation** **Cryopreservation of sperm, semen or embryos is proven and medically necessary for individuals who are undergoing treatment with assisted reproductive technologies or are planning to undergo therapies that threaten their reproductive health, such as cancer chemotherapy.** **Cryopreservation of *mature* oocytes (eggs) is proven and medically necessary for women, under the age of 42, who are undergoing treatment with assisted reproductive technologies or are planning to undergo therapies that threaten their reproductive health,**

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Title	Effective Date	Summary of Changes	Coverage Rationale
Infertility Diagnosis and Treatment *(continued)*	Aug. 1, 2014		**such as cancer chemotherapy.** **Cryopreservation of *immature* oocytes (eggs) is unproven and not medically necessary.** **Further evidence from well-designed trials is needed to determine the long-term safety and efficacy of cryopreserving immature oocytes for future in vitro maturation.** **Cryopreservation of ovarian or testicular tissue is unproven and not medically necessary.** Ovarian tissue banking remains a promising clinical technique because it avoids ovarian stimulation and provides the opportunity for preserving gonadal function in prepubertal, as well as adult patients. However, this procedure has produced very few live births. Testicular tissue or testis xenografting are in the early phases of experimentation and have not yet been successfully tested in humans.
Light and Laser Therapy for Cutaneous Lesions and Pilonidal Disease	Aug. 1, 2014	• Changed policy title; previously titled *Laser Therapy for Cutaneous Vascular Lesions and Pilonidal Disease* • Reorganized policy content o Updated benefit considerations; added language for *Essential Health Benefits for Individual and Small Group* plans to indicate: o For plan years beginning on or after January 1, 2014, the Affordable Care Act of 2010 (ACA) requires fully insured non-grandfathered individual and small group plans (inside and outside of Exchanges) to provide coverage for ten categories of Essential Health Benefits ("EHBs") o Large group plans (both self-funded and fully insured), and small group	**Cutaneous Lesions** **Pulsed dye laser therapy is proven and medically necessary for the treatment of port-wine stains and cutaneous hemangiomata.** **Light and laser therapy including intense pulsed light are unproven and not medically necessary for the treatment of rosacea and rhinophyma.** The quantity and quality of the evidence is insufficient to recommend light and laser treatment for the treatment of rosacea and rhinophyma. The quality of evidence is limited. Additional research is needed to determine efficacy and safety and to clarify patient selection and treatment parameters. **Light and laser therapy including light phototherapy, photodynamic therapy, intense pulsed light, and pulsed dye laser are unproven and not medically necessary for treating active acne vulgaris.** There is insufficient evidence to recommend the use of light and laser

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Title	Effective Date	Summary of Changes	Coverage Rationale
Light and Laser Therapy for Cutaneous Lesions and Pilonidal Disease *(continued)*	Aug. 1, 2014	ASO plans, are not subject to the requirement to offer coverage for EHBs; however, if such plans choose to provide coverage for benefits which are deemed EHBs (such as maternity benefits), the ACA requires all dollar limits on those benefits to be removed on all Grandfathered and Non-Grandfathered plans o The determination of which benefits constitute EHBs is made on a state by state basis; as such, when using this guideline, it is important to refer to the enrollee's specific plan document to determine benefit coverage • Revised coverage rationale: o Added language to indicate if service is "medically necessary" or "not medically necessary" to existing proven/ unproven statements o Replaced language indicating "laser therapy including intense pulsed light is unproven for the treatment of rosacea" with "light and laser therapy including intense pulsed light are unproven and not medically necessary for the treatment of rosacea and rhinophyma" o Added language to indicate light and laser therapy including light phototherapy, photodynamic therapy, intense pulsed light, and pulsed dye laser are unproven and not medically necessary for treating active acne vulgaris	therapy for the treatment acne vulgaris. Studies evaluating light and laser therapy for acne typically are short term, lack controls or the patient serves as their own control, have small sample sizes, and do not compare laser therapy with standard acne treatment. Well-designed studies are necessary to clarify the role of light and laser therapy for acne. **Pilonidal Sinus Disease** **Laser hair removal is unproven and not medically necessary for the treatment of pilonidal sinus disease.** There is insufficient evidence to conclude that laser hair removal is effective for treating pilonidal sinus disease. Most of the studies regarding this treatment were small and uncontrolled. Additional well-designed controlled trials are needed to determine the efficacy of laser hair removal for pilonidal disease.

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Title	Effective Date	Summary of Changes	Coverage Rationale
Light and Laser Therapy for Cutaneous Lesions and Pilonidal Disease *(continued)*	Aug. 1, 2014	• Updated list of applicable ICD-9 diagnosis codes; added 706.1 • Updated list of applicable ICD-10 diagnosis codes (preview draft effective 10/01/15): o Reorganized code listings by diagnosis category o Added L70.0, L70.1, L70.3, L70.4, L70.5, L70.8, L70.9 and L73.0 • Updated supporting information to reflect the most current description of services, clinical evidence, FDA and CMS information and references	
Outpatient Cardiovas-cular Telemetry	Aug. 1, 2014	• Revised coverage rationale; added language to indicate: o Standard cardiac event monitoring must be of sufficient duration to detect a cardiac arrhythmia under consideration o Event monitors may be used for a short duration (e.g., 24-48 hours) or for a longer period (e.g., 14-30 days or longer) o A physician who suspects an occult arrhythmia will order event monitoring for a longer time period; therefore, non-diagnostic 24-48 hour Holter monitoring to detect a cardiac arrhythmia would not be an indication for outpatient cardiovascular telemetry	**Outpatient cardiovascular telemetry is proven and medically necessary for the following indications:** • Suspected cardiac arrhythmia not detected with standard cardiac event monitoring* • Cryptogenic stroke with suspected occult atrial fibrillation as the cause of the stroke • Monitoring arrhythmia status following an ablation procedure * Standard cardiac event monitoring includes non-implantable cardiac event monitors that record cardiac events for days, weeks or months. Event recording may be patient activated or automatically collected. The patient then periodically telephones events to a central collection area. Standard cardiac event monitoring must be of sufficient duration to detect a cardiac arrhythmia under consideration. Event monitors may be used for a short duration (e.g., 24-48 hours) or for a longer period (e.g., 14-30 days or longer). A physician who suspects an occult arrhythmia will order event monitoring for a longer time period; therefore, non-diagnostic 24-48 hour Holter monitoring to detect a cardiac arrhythmia would not be an indication for outpatient cardiovascular telemetry.

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RETIRED		
Title	**Effective Date**	**Summary of Changes**
Transtympanic Micropressure	Jul. 1, 2014	• Policy retired; transtympanic micropressure is now covered without need for clinical review

Drug Policy Updates

NEW

Title	Effective Date	Coverage Rationale
Soliris (Eculizumab)	Oct. 1, 2014	Eculizumab is **proven** for treatment of: 1) Atypical hemolytic uremic syndrome (aHUS) 2) Paroxysmal nocturnal hemoglobinuria (PNH) **Additional information to support medical necessity review where applicable:** The above indications and criteria also apply to medical necessity review. Eculizumab is **unproven** for treatment of Shiga toxin E. coli-related hemolytic uremic syndrome (STEC-HUS). **Centers for Medicare and Medicaid Services (CMS):** Medicare does not have a National Coverage Determination (NCD) that addresses Eculizumab (Soliris™). Medicare covers outpatient (Part B) drugs that are furnished "incident to" a physician's service provided that the drugs are not usually self-administered by the patients who take them. See the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals at http://www.cms.hhs.gov/manuals/Downloads/bp102c15.pdf. Local Coverage Determinations (LCDs) exist for Eculizumab (Soliris™). Refer to the LCDs for Drugs and Biologics (Non-chemotherapy). (Accessed May 6, 2014)

UPDATED

Title	Effective Date	Summary of Changes
Benlysta (Belimumab)	Aug. 1, 2014	• Updated description of services to reflect the most current clinical evidence, FDA and CMS information, and references; no change to coverage rationale or lists of applicable codes • Updated list of applicable ICD-10 codes (preview draft effective 10/01/15); changed tentative effective date of ICD-10 code set implementation from "10/01/14" to "10/01/15"
Mifeprex (Mifepristone, RU-486)	Aug. 1, 2014	• Updated description of services to reflect the most current CMS information and references; no change to coverage rationale or lists of applicable codes

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Title	Effective Date	Summary of Changes
17-Alpha-Hydroxypro-gesterone Caproate (Makena™ and 17P)	Aug. 1, 2014	• Updated coverage rationale: o Reformatted information pertaining to medical necessity review to indicate criteria applies to all requests for Makena and 17P o Added language to indicate the unproven indications are "not medically necessary" • Updated list of applicable ICD-10 codes (preview draft effective 10/01/15): o Changed tentative effective date of ICD-10 code set implementation from "10/01/14" to "10/01/15" o Removed Z3A.16 - Z3A.36 • Updated supporting information to reflect the most current clinical evidence, CMS information and references

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Title	Effective Date	Summary of Changes
Repository Corticotropin Injection (H.P. Acthar Gel®)	Aug. 1, 2014	• Revised coverage rationale: o Changed coverage status for the following diagnosis from "proven and medically necessary" to "unproven and not medically necessary": ▪ Rheumatic Disorders: Psoriatic arthritis, rheumatoid arthritis, including juvenile rheumatoid arthritis, ankylosing spondylitis ▪ Collagen Diseases: Systemic lupus erythematosus, systemic dermatomyositis (polymyositis) ▪ Dermatologic Diseases: Severe erythema multiforme, Stevens-Johnson syndrome ▪ Allergic States: Serum sickness ▪ Ophthalmic Diseases: Severe acute and chronic allergic and inflammatory processes involving the eye and its adnexa such as keratitis, iritis, iridocyclitis, diffuse posterior uveitis and choroiditis, optic neuritis, chorioretinitis, anterior segment inflammation ▪ Respiratory Diseases: Symptomatic sarcoidosis ▪ Edematous State: To induce a diuresis or a remission of proteinuria in the nephrotic syndrome without uremia of the idiopathic type or that due to lupus erythematosus ▪ Any indication not listed as medically necessary o Changed coverage status for the following diagnosis from "proven and medically necessary" to "proven and not medically necessary": ▪ Multiple sclerosis (MS), acute exacerbation • Updated list of applicable ICD9 codes; removed 135, 340, 363.00, 363.01, 363.03, 363.04, 363.05, 363.06, 363.07, 363.08, 363.10, 363.11, 363.12, 363.13, 363.14, 363.15, 363.20, 363.21, 363.22, 364.00, 364.01, 364.02, 364.03, 364.04, 364.05, 364.10, 364.11, 364.21, 364.22, 364.23, 364.24, 364.3, 377.30, 377.31, 377.32, 377.33, 377.34, 377.39, 379.59, 581.0, 581.1, 581.2, 581.3, 581.81, 581.89, 581.9, 695.13, 696.0, 710.0, 710.4, 714.0, 714.30, 714.31, 714.32, 714.33 and 720.0 • Updated list of applicable ICD-10 codes (preview draft effective 10/01/15): o Changed tentative effective date of ICD-10 code set implementation from "10/01/14" to "10/01/15" o Added G40.821, G40.822, G40.823 and G40.824 o Removed A18.53, A18.54, D86.0, D86.1, D86.2, D86.3, D86.81, D86.82, D86.83, D86.84, D86.85, D86.86, D86.87, D86.89, D86.9, G35, G40.401, G40.409, G40.411, G40.419, H20.00, H20.011, H20.012, H20.013, H20.019, H20.021, H20.022, H20.023, H20.029, H20.031, H20.032, H20.033, H20.039, H20.041, H20.042, H20.043, H20.049, H20.051, H20.052, H20.053, H20.059, H20.10, H20.11, H20.12, H20.13, H20.20, H20.21, H20.22, H20.23, H20.811, H20.812, H20.813, H20.819, H20.821, H20.822, H20.823, H20.829, H20.9, H20.9, H30.001, H30.002, H30.003, H30.009, H30.011, H30.012, H30.013, H30.019, H30.021, H30.022, H30.023, H30.029, H30.031, H30.032, H30.033, H30.039, H30.041, H30.042, H30.043, H30.049, H30.101, H30.101, H30.102, H30.102, H30.103, H30.103, H30.109, H30.109, H30.111, H30.112, H30.113, H30.119, H30.121, H30.122, H30.123, H30.129, H30.131, H30.132, H30.133, H30.139, H30.141, H30.142, H30.143, H30.149, H30.20, H30.21, H30.22, H30.23, H30.811, H30.812, H30.813, H30.819, H30.891, H30.892, H30.893, H30.899, H30.90, H30.91, H30.92, H30.93, H40.40X0, H46.00, H46.01, H46.02, H46.03, H46.10, H46.11, H46.12, H46.13, H46.2, H46.3, H46.8, H46.9, H55.89, L40.50, L40.51, L40.52,

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REVISED

Title	Effective Date	Summary of Changes
Repository Corticotropin Injection (H.P. Acthar Gel®) *(continued)*	Aug. 1, 2014	L40.53, L40.54, L40.59, L51.1, M05.40, M05.411, M05.412, M05.419, M05.421, M05.422, M05.429, M05.431, M05.432, M05.439, M05.441, M05.442, M05.449, M05.451, M05.452, M05.459, M05.461, M05.462, M05.469, M05.471, M05.472, M05.479, M05.49, M05.50, M05.511, M05.512, M05.519, M05.521, M05.522, M05.529, M05.531, M05.532, M05.539, M05.541, M05.542, M05.549, M05.551, M05.552, M05.559, M05.561, M05.562, M05.569, M05.571, M05.572, M05.579, M05.59, M05.70, M05.711, M05.712, M05.719, M05.721, M05.722, M05.729, M05.731, M05.732, M05.739, M05.741, M05.742, M05.749, M05.751, M05.752, M05.759, M05.761, M05.762, M05.769, M05.771, M05.772, M05.779, M05.79, M05.80, M05.811, M05.812, M05.819, M05.821, M05.822, M05.829, M05.831, M05.832, M05.839, M05.841, M05.842, M05.849, M05.851, M05.852, M05.859, M05.861, M05.862, M05.869, M05.871, M05.872, M05.879, M05.89, M05.9, M06.00, M06.011, M06.012, M06.019, M06.021, M06.022, M06.029, M06.031, M06.032, M06.039, M06.041, M06.042, M06.049, M06.051, M06.052, M06.059, M06.061, M06.062, M06.069, M06.071, M06.072, M06.079, M06.08, M06.09, M06.20, M06.211, M06.212, M06.219, M06.221, M06.222, M06.229, M06.231, M06.232, M06.239, M06.241, M06.242, M06.249, M06.251, M06.252, M06.259, M06.261, M06.262, M06.269, M06.271, M06.272, M06.279, M06.28, M06.29, M06.30, M06.311, M06.312, M06.319, M06.321, M06.322, M06.329, M06.331, M06.332, M06.339, M06.341, M06.342, M06.349, M06.351, M06.352, M06.359, M06.361, M06.362, M06.369, M06.371, M06.372, M06.379, M06.38, M06.39, M06.80, M06.811, M06.812, M06.819, M06.821, M06.822, M06.829, M06.831, M06.832, M06.839, M06.841, M06.842, M06.849, M06.851, M06.852, M06.859, M06.861, M06.862, M06.869, M06.871, M06.872, M06.879, M06.88, M06.89, M06.9, M08.00, M08.011, M08.012, M08.019, M08.021, M08.022, M08.029, M08.031, M08.032, M08.039, M08.041, M08.042, M08.049, M08.051, M08.052, M08.059, M08.061, M08.062, M08.069, M08.071, M08.072, M08.079, M08.08, M08.09, M08.1, M08.20, M08.211, M08.212, M08.219, M08.221, M08.222, M08.229, M08.231, M08.232, M08.239, M08.241, M08.242, M08.249, M08.251, M08.252, M08.259, M08.261, M08.262, M08.269, M08.271, M08.272, M08.279, M08.28, M08.29, M08.3, M08.40, M08.40, M08.411, M08.412, M08.419, M08.421, M08.422, M08.429, M08.431, M08.432, M08.439, M08.441, M08.442, M08.449, M08.451, M08.452, M08.459, M08.461, M08.462, M08.469, M08.471, M08.472, M08.479, M08.48, M08.80, M08.811, M08.812, M08.819, M08.821, M08.822, M08.829, M08.831, M08.832, M08.839, M08.841, M08.842, M08.849, M08.851, M08.852, M08.859, M08.861, M08.862, M08.869, M08.871, M08.872, M08.879, M08.88, M08.89, M08.90, M08.911, M08.912, M08.919, M08.921, M08.922, M08.929, M08.931, M08.932, M08.939, M08.941, M08.942, M08.949, M08.951, M08.952, M08.959, M08.961, M08.962, M08.969, M08.971, M08.972, M08.979, M08.98, M08.99, M32.0, M32.10, M32.11, M32.12, M32.13, M32.14, M32.15, M32.19, M32.8, M32.9, M33.20, M33.21, M33.22, M33.29, M45.0, M45.1, M45.2, M45.3, M45.4, M45.5, M45.6, M45.7, M45.8, M45.9,

Drug Policy Updates

REVISED		
Title	**Effective Date**	**Summary of Changes**
Repository Corticotropin Injection (H.P. Acthar Gel®) *(continued)*	Aug. 1, 2014	M48.8X1, M48.8X2, M48.8X3, M48.8X4, M48.8X5, M48.8X6, M48.8X7, M48.8X8, M48.8X9, N02.0, N02.1, N02.2, N02.3, N02.4, N02.5, N02.6, N02.7, N02.8, N02.9, N04.0, N04.1, N04.2, N04.3, N04.4, N04.5, N04.6, N04.7, N04.8, N04.9, N08, T80.61XA and T80.69XA • Updated supporting information to reflect the most current clinical evidence, CMS information and references
Tysabri (Natalizum-ab)	Aug. 1, 2014	• Revised coverage rationale: o Updated coverage criteria; added criterion requiring baseline cranial MRI to be performed prior to initial administration o Added language to clarify natalizumab is unproven for treatment of types of MS other than relapsing forms • Updated list of applicable ICD-10 codes (preview draft effective 10/01/15); changed tentative effective date of ICD-10 code set implementation from "10/01/14" to "10/01/15" • Updated supporting information to reflect the most current clinical evidence, CMS and FDA information, and references

Utilization Review Guideline (URG) Updates

NEW

Title	Effective Date	Coverage Rationale
Site of Care Review Guidelines for Medical Necessity of Hospital Outpatient Facility Specialty Medication Infusion	Oct. 1, 2014	**Introduction** This guideline addresses the criteria for consideration of allowing hospital outpatient facility specialty medication infusion service and claim submission for hospital based services with CMS/AMA Place of Service code 22 therapy. This Policy applies to these specialty medications that require healthcare provider infusion: • Eculizumab (Soliris®) **Review Criteria for Site of Care Selection** Hospital facility-based intravenous medication infusion is medically necessary for persons who meet any of the following criteria: • Medically unstable based upon submitted clinical history; OR • Initial medication infusion of or re-initiation after more than 6 months following discontinuation of therapy; OR • Previous experience of a severe adverse event following infusion. Examples include but are not limited to anaphylaxis, seizure, thromboembolism, myocardial infarction, renal failure; OR • Continuing experience of adverse events that cannot be mitigated by pre-medications; OR • Physically and/or cognitively impaired AND no home caregiver available. **Additional information:** Medical necessity criteria for administration of intravenous infusion therapy at home are addressed in MCG CMT-0009 "Home Infusion Therapy." **Benefit Considerations** This guideline applies to members with 2011 COC or Summary Plan Document with benefits available for health care services if medically necessary and have been approved for the requested medication clinical use. This guideline applies to UHC Commercial and Medicaid plans. This guideline does not apply to Medicare plans. **Supporting Information and Clinical Evidence** **Background:** Home infusion as a place of service is well established and accepted by physicians. A 2010 home infusion provider survey by the National Home Infusion Association reported providing 1.24 million therapies to approximately 829,000 patients, including 129,071 infusion therapies of specialty medications. **Clinical Evidence:** MCG Guideline CMT-0009 "Home Infusion Therapy" guideline addresses criteria for home infusion therapy. Clinical patient characteristics for home suitability include: clinical stability, no need for close observation or daily nurse care, and reliable venous access. Additional criteria for home environment, infusion plan and patient ability to participate in care are summarized. **Professional Societies:** The American Academy of Allergy Asthma and Immunology has published guidelines for the suitability of patients to receive treatment in various care setting including clinical characteristics of patients needing a high level of care in the hospital outpatient facility which includes patient characteristics:

Utilization Review Guideline (URG) Updates

NEW

Title	Effective Date	Coverage Rationale
Site of Care Review Guidelines for Medical Necessity of Hospital Outpatient Facility Specialty Medication Infusion *(continued)*	Oct. 1, 2014	previous serious infusion reaction such as anaphylaxis, seizure, myocardial infarction, or renal failure, immune globulin therapy naïve, continual experience of moderate or serious infusion related adverse reactions, physical or cognitive impairment. The Hunter Syndrome European Expert Council: European recommendations for the diagnosis and multidisciplinary management of a rare disease published an article reviewing the collective experiences with agalsidase beta home infusion therapy and outlines how safe, patient-centered homecare can be organized in enzyme replacement therapy for patients with Fabry disease. Criteria include that "Patients must have received ERT in hospital for 3-6 months; if patients have previously had IRRs, they must be under control with premedication, and they must not have had an IRR in the 2-8 weeks before homecare is approved and premedication must be given. If a patient has significant respiratory disease (%FVC, 40% or less; or evidence of serious obstructive airway disease), homecare may not be suitable." The Agency for Healthcare Research and Quality (AHRQ) publication on Enzyme Replacement Therapy states, "Home infusion of ERT was initially studied in patients with type I Gaucher disease. It has been reported as an option for patients with Fabry disease, MPS I, and MPS II, and MPS VI. However, patients with infantile Pompe disease may not be able to transfer to home care because of an increased risk for serious adverse events during an infusion. In general, the outcomes measured in these studies and the follow-up durations were similar to those reported by disease in the clinical studies summarized under Guiding Question 3. Safety was the main focus of most home infusion studies, as the patients had already been receiving ERT in a more controlled setting." **Medication or Condition Specific Studies:** Eculizumab - Paroxysmal Nocturnal Hemoglobinuria In a trial evaluating patients with paroxysmal nocturnal hemoglobinuria, after initial 2-5 doses of eculizumab (Soliris), 79 patients received continued infusion with every 14 days in the home setting for the duration of the study – 1-98 months, mean duration of 39 months. The survival of patients treated with eculizumab was not different from age- and sex-matched normal controls (P = .46) but was significantly better than 30 similar patients managed before eculizumab (P = .030). Three patients on eculizumab, all over 50 years old, died of causes unrelated to PNH. Twenty-one patients (27%) had a thrombosis before starting eculizumab (5.6 events per 100 patient-years) compared with 2 thromboses on eculizumab (0.8 events per 100 patient-years; P < .001). Twenty-one patients with no previous thrombosis discontinued warfarin on eculizumab with no thrombotic sequelae. Forty of 61 (66%) patients on eculizumab for more than 12 months achieved transfusion independence. The 12-month mean transfusion requirement reduced from 19.3 units before eculizumab to 5.0 units in the most recent 12 months on eculizumab (P < .001). Eculizumab dramatically alters the natural course of PNH, reducing symptoms and disease complications as well as improving survival to a similar level to that of the general population.