I. POLICY

H.P. Acthar Gel (repository corticotropin injection) is indicated as monotherapy for the treatment of infantile spasms in infants and children under 2 years of age. H.P. Acthar Gel is also indicated for the treatment of exacerbations of multiple sclerosis (MS) in adults.

Infantile spasms

H.P. Acthar Gel is medically necessary for members who meet the following criteria:

- A diagnosis of infantile spasms and less than 2 years of age.
- Does not have a suspected congenital infection.
- Has shown substantial clinical benefit if currently receiving therapy.

Multiple Sclerosis

H.P. Acthar Gel for exacerbations of multiple sclerosis is medically necessary for members who meet the following criteria:

- None of the following contraindications:
  - scleroderma, osteoporosis, systemic fungal infections, ocular herpes simplex, recent surgery, history of or the presence of a peptic ulcer, congestive heart failure, uncontrolled hypertension, or sensitivity to proteins of porcine origin
- Has tried one of the following standard therapies of multiple sclerosis:
  - Avonex (interferon beta-1a), Betaseron (interferon beta-1b), Extavia (interferon beta-1b), Rebif (interferon beta-1a), Copaxone (glatiramer acetate), Gilenya (fingolimod), Aubagio (teriflunomide), Tysabri (natalizumab)
- Tried and failed or is intolerant to parenteral corticosteroids or has poor intravenous access.
H.P. Acthar Gel is not recommended in the following situations:

- Has received or will receive a live or live attenuated vaccine within 6 weeks of H.P. Acthar Gel administration.
- Does not meet the conditions listed above.

Cross-reference:

MP-2.103 Off-Label Use of Medications

II. PRODUCT VARIATIONS

This policy is applicable to all programs and products administered by Capital BlueCross unless otherwise indicated below.

FEP PPO*

*Refer to FEP Medical Policy Manual MP-5.08.10 H.P. Acthar Gel. The FEP Medical Policy manual can be found at: [www.fepblue.org](http://www.fepblue.org)

Note for Medicare Advantage:

1. FDA approved drugs used for indications other than what is indicated on the FDA approved product label may be covered under Medicare if it is determined that the use is medically accepted, taking into consideration the Medicare recognized national drug compendia, authoritative medical literature and/or accepted standards of medical practice.” Refer to Medicare Benefit Policy Manual (100-2, Chapter 15, Section 50.4.2- Unlabeled Use of Drug). [http://www.cms.gov/manuals/Downloads/bp102c15.pdf](http://www.cms.gov/manuals/Downloads/bp102c15.pdf)

2. In accordance with CMS letter issued on September 17, 2012, entitled “Prohibition on Imposing Mandatory Step Therapy for Access to Part B Drugs and Services”. Step therapy that is not part of the FDA label does not apply to Medicare Advantage.

III. DESCRIPTION/BACKGROUND

Repository corticotropin intramuscular or subcutaneous injection has primarily been used for treating infantile spasms (West syndrome). It has also been investigated for diagnostic testing of adrenocortical function and for treating a variety of other conditions.

Repository corticotropin injection (H.P. Acthar® gel, Questcor Pharmaceuticals, Union City, CA) is a purified, sterile preparation of the natural form of adrenocorticotropic hormone (ACTH) in gelatin to provide a prolonged release after intramuscular or subcutaneous injection. ACTH is
produced and secreted by the pituitary gland; H.P. Acthar gel uses ACTH obtained from porcine pituitaries. ACTH works by stimulating the adrenal cortex to produce cortisol, corticosterone, and a number of other hormones.

H.P. Acthar gel was approved by the U.S. Food and Drug Administration (FDA) in 1952, before there was a requirement that companies provide clinical evidence of efficacy. The product label states that Acthar gel is indicated for a number of conditions, listed below.

According to the prescribing information (i.e. product label), repository corticotropin injection may be used in the treatment of the following conditions (1):
1.1 Infantile Spasms in infants and children younger than 2 years of age.
1.2 Multiple Sclerosis: Treatment of acute exacerbations of multiple sclerosis in adults. (indication added in 1978).
1.3 Rheumatic Disorders: Adjunctive therapy for patients with acute episodes or exacerbations of psoriatic arthritis, rheumatoid arthritis and ankylosing spondylitis.
1.4 Collagen Diseases: Treatment of selected cases of systemic lupus erythematosus and systemic dermatomyositis.
1.5 Dermatologic Diseases: Treatment of severe erythema multiforme and Stevens-Johnson syndrome.
1.6 Allergic States: Treatment of serum sickness.
1.7 Ophthalmic Diseases: Treatment of severe acute and chronic allergic and inflammatory processes including optic neuritis, keratitis and iritis.
1.8 Respiratory Diseases: Treatment of symptomatic sarcoidosis)
1.9 Edematous State: Treatment of proteinuria in the nephrotic syndrome without uremia of the idiopathic type or due to lupus erythematosus.

Among the above indications, repository corticotrophin injection is best known for the treatment of infantile spasms. This is a rare epileptic disorder of infancy (90% of cases are diagnosed in the first year of life). When infantile spasms are accompanied by neurodevelopmental regression and electroencephalogram (EEG) findings of hypsarrhythmia, the condition is known as West syndrome. Vigabatrin oral solution is another available treatment for infantile spasms.

Multiple sclerosis (MS) is a chronic disease of the nervous system which affects young and middle-aged adults. A disruption in the ability of the nerves to conduct electrical impulses to and from the brain produces the many symptoms of MS which can lead to permanent disability. Corticosteroids are taken to reduce the inflammation caused by these disruptions.

Diagnostic testing of adrenocortical function, known as the ACTH test, is typically done with synthetic ACTH. Synthetic ACTH products have been approved by the FDA for this purpose. Unlike previous versions of the H.P. Acthar product label, an updated label issued in 2010, did not mention the use of repository corticotropin injection for diagnostic testing of adrenocortical function.
A synthetic derivative of ACTH is commercially available outside of the United States (under the tradenames Cortosyn and Synacthen) but it is not approved by the FDA for any of the conditions currently included in the H.P. Acthar gel FDA-approved label. In addition, a depot formulation of ACTH (Synacthen Depot) is available through a compassionate-use program through the specialty pharmacy Caligor Rx in New York. In June 2013, Questcor Pharmaceuticals announced that they acquired the rights to market Synacthen in the United States, once FDA approval is obtained.

Repository corticotropin injection has potential adverse effects similar to those that occur with steroid medication such as elevated blood pressure, decrease in bone density, new infections or activation of previous infection, and overproduction of cortisol, which can cause symptoms of Cushing’s syndrome.

Regulatory Status

H.P. Acthar gel (Questcor Pharmaceuticals) was approved by the FDA in 1952. The product label states that Acthar gel is indicated for 19 conditions, including infantile spasms. Contraindications for use of this agent include scleroderma, osteoporosis, systemic fungal infections, ocular herpes simplex, recent surgery, history of or the presence of a peptic ulcer, congestive heart failure, uncontrolled hypertension, or sensitivity to proteins of porcine origin. Unlike previous versions of the product label, an updated label issued in 2010, did not include the use of repository corticotropin injection for diagnostic testing of adrenocortical function.

IV. RATIONALE

This evidence review was originally created in February 2008 and has been updated regularly with searches of the MEDLINE database. Most recently, the literature was reviewed through November 13, 2015. Following is a summary of the key literature to date.

Evidence that Acthar Gel (ie, ACTH) is a reasonable alternative to corticosteroid treatment requires controlled studies demonstrating superiority or noninferiority of ACTH to corticosteroids as first-line treatment, or controlled studies showing comparable efficacy of ACTH with fewer adverse effects. Randomized controlled studies are crucial to avoid noncomparability of treatment groups. Alternatively, for patients unable to tolerate corticosteroids, the most appropriate study design would be a controlled study comparing ACTH with placebo.

Infantile Spasms

In 2013, Hancock et al published an updated Cochrane review on medication treatment of infantile spasms. The authors identified 18 randomized controlled trials (RCTs) investigating a total of 12 different medications. The overall quality of studies was deemed to be poor (ie, fewer than half of the studies reported the method of randomization, and only 2 had more than 100 participants). A total of 5 studies compared treatment with adrenocorticotropic hormone (ACTH)
Policy Title: Repository Corticotropin Injection (H.P. Acthar Gel)  
Policy Number: MP-2.162

with another medication. The review authors did not differentiate between synthetic and natural forms of ACTH. Two studies compared ACTH with vigabatrin (total sample sizes 9 and 42, respectively), 2 compared ACTH to prednisone (n=29 and 24, respectively), and 1 study with 52 participants compared ACTH with nitrazepam. A sixth study compared vigabatrin and ACTH in a subset of patients. Dosages and treatment regimens varied. The authors conducted several quantitative meta-analyses. A pooled analysis of 3 studies found that symptom resolution occurred in 30 of 45 patients (67%) responding to vigabatrin and 40 of 49 patients (82%) responding to ACTH. The difference between groups was statistically significant (odds ratio, 0.38; 95% confidence interval, 0.15 to 0.99). The authors noted that the limited evidence from RCTs suggests that hormonal treatment (prednisolone, tetracosactide depot and ACTH) resolves infantile spasms faster than vigabatrin and resolves the condition in more children, but long-term developmental and epilepsy outcomes are unknown.

Since the Cochrane review, in 2014, a RCT was published that assigned children with previously untreated infantile spasms to treatment with 40 to 60 IU synthetic ACTH every other day or 40 to 60 mg/day of oral prednisolone. The study was conducted in Sri Lanka and uses a form of ACTH that is not approved by the U.S. Food and Drug Administration for this indication. The primary outcome, assessed in a blinded fashion after a 14-day treatment period, was change in a hypsarrhythmia severity scale (possible score range, 0-16). Hypsarrhythmia is an abnormal interictal pattern seen on an electroencephalogram and can be considered an intermediate outcome; clinical outcomes such as symptom resolution were not assessed. Ninety-two children were randomized, and follow-up data were available on 80 (82%) of them. Mean improvement in the hypsarrhythmia score was 7.95 (SD=2.76) in the prednisolone arm and 6.00 (SD=2.61) in the ACTH arm. The between-group difference was significantly different (p<0.01), favoring treatment with prednisolone. Rates of adverse effects were similar in the 2 groups. This study suggests that prednisolone may at least be as effective as synthetic ACTH for treatment of infantile spasms. However, the study has methodologic limitations including a dropout rate of over 20%, lack of intention-to-treat analysis, short-term follow-up only, and use of intermediate outcomes.

**Section Summary: Infantile Spasms**
There is some evidence from small, generally poor quality RCTs, that natural and synthetic ACTH has greater short-term efficacy in resolving infantile spasms than vigabatrin. A 2014 RCT suggests that prednisolone may be at least as effective in the short term as synthetic ACTH in the treatment of infantile spasms.

**Corticosteroid-Responsive Conditions**
The product label for H.P. Acthar Gel (ie, ACTH) lists a number of corticosteroid-responsive conditions as indications for repository corticotropin injection, including rheumatoid arthritis, dermatomyositis, symptomatic sarcoidosis, nephrotic syndrome, multiple sclerosis (MS) exacerbations, and serum sickness. The only controlled studies found were for the treatment of MS (ie, not for other indications). Several RCTs published in the 1960s and early 1970s compared ACTH with placebo for the treatment of acute exacerbations of MS. A study described in recent review articles as the most rigorous of these RCTs was published by Rose et al. This
was a multicenter, double-blind study that included 197 patients. Patients were randomized to receive intramuscular injections of ACTH gel or placebo during a 2-week hospitalization for acute exacerbations of MS. The study used Depo-ACTH and placebo, both prepared by the Upjohn Company. Review articles report that the study found that ACTH hastened improvement in symptoms but that the differences between the ACTH and placebo-treated patients were less marked as the dosage of ACTH was reduced during the second week of treatment.\(^6\)

Use of ACTH for treating MS exacerbations decreased in the 1980s as intravenous (IV) corticosteroid treatment became more common. Two RCTs published in the late 1980s compared ACTH with IV corticosteroids. A study by Milanese et al with 30 patients found that dexamethasone was more effective than ACTH in shortening the length of the exacerbation.\(^7\) Thompson et al published a study that included 61 patients and compared ACTH and high-dose IV methylprednisolone.\(^8\) The authors did not find a statistically significant difference in the efficacy of the 2 treatments. The study was powered to detect a 1-point difference between the 2 groups on the Kurtzke function and disability scales. The scores before and after treatment were not reported.

There are also a limited number of small case series reporting on use of ACTH for other corticosteroid-responsive conditions. For example, in 2011, Bomback et al published a retrospective case series in 21 patients with idiopathic, non-diabetic nephrotic syndrome who were treated with ACTH gel. ACTH gel was used as a primary therapy in 3 patients; the other 18 patients had failed a mean of 2.3 immunosuppressive regimens before using ACTH gel.\(^9\) An additional 5 patients were identified who were treated for less than 6 months and were taken off therapy for lack of response; these patients were not included in the analysis. Four of the 21 (19%) patients were in complete remission, defined as stable or improved renal function with final proteinuria falling to less than 500 mg/d. An additional 7 of 21 (33%) patients had a partial remission (at least a 50% reduction in proteinuria and final proteinuria 500-3500 mg/d).

**Section Summary: Corticosteroid-Responsive Conditions**

There is insufficient evidence that ACTH gel is at least as effective as IV corticosteroids for treatment of MS. One of 2 RCTs found that corticosteroids were more effective and the other found no significant difference in efficacy. There is a lack of evidence from controlled trials that ACTH is an effective treatment of other corticosteroid-responsive conditions.

**Diagnostic Testing of Adrenocortical Function**

Diagnostic testing of adrenocortical function is typically done with synthetic ACTH. Studies have evaluated the value of synthetic ACTH for diagnosing adrenal insufficiency. For example, a 2008 meta-analysis identified 13 studies comparing low- and high-dose corticotropin tests for diagnosing adrenal insufficiency.\(^10\) A comparable literature base was not identified for use of H.P. Acthar gel used in the diagnostic testing of adrenocortical function, and no studies were found that compared synthetic ACTH and Acthar gel for this purpose.

**Non-Corticosteroid-Responsive Conditions**

Repository corticotropin injection has also been proposed for several off-label non-corticosteroid-responsive conditions including tobacco cessation, acute gout, and childhood
epilepsy. Controlled studies were identified only for treatment of acute gout. In 2008, Janssens et al published a Cochrane review that examined the efficacy and safety of systemic corticosteroids in the treatment of acute gout in comparison with placebo, nonsteroidal anti-inflammatory drugs, colchicine, other active drugs, other therapies including repository corticotropin injection, or no therapy. Three head-to-head trials were identified; one of these compared systemic corticosteroids with oral indomethacin and intramuscular ACTH. The quality of the 3 studies identified was graded as very low to moderate. None of the studies found clinically relevant differences between the studied systemic corticosteroids and the comparator drugs and important safety problems attributable to the used corticosteroids were not reported. The authors concluded that “There is inconclusive evidence for the efficacy and effectiveness of systemic corticosteroids in the treatment of acute gout.”

Section Summary: Non-Corticosteroid-Responsive Conditions
There is insufficient evidence from controlled trials that ACTH is a safe and effective treatment of non-corticosteroid-responsive treatments.

Other
A study done by Lal et al looked at the pharmacodynamics and tolerability of repository corticotropin injection (ACTH) compared to IV methylprednisolone (IVMP). This was a multiple-dose, randomized, open-label crossover study that enrolled 18 healthy subjects to evaluate the total cortisol-equivalent exposure, effects on circulating immune cells, and tolerability of the study drug used. The authors concluded that ACTH may cause less systemic immunosuppression relative to equivalent doses of IVMP, which may be of benefit in autoimmune disorders, such as MS. This is a small study done in healthy subjects, which offered no clinical outcomes. Further studies are needed to substantiate these findings.

Ongoing and Unpublished Clinical Trials
Some currently unpublished trials that might influence this review are listed in Table 1.
Table 1. Summary of Key Trials

<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
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<td>NCT01753401a</td>
<td>A Two-part Study Exploring the Efficacy, Safety, and Pharmacodynamics of Acthar in Systemic Lupus Erythematosus Patients With a History of Persistently Active Disease</td>
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<td>Dec 2015</td>
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<tr>
<td>NCT01601236a</td>
<td>A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Adaptive Design Pilot Safety and Efficacy Study of H.P. Acthar Gel (Acthar) in Patients With Diabetic Nephropathy and Proteinuria</td>
<td>40</td>
<td>Jan 2016</td>
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<tr>
<td>NCT02290444</td>
<td>Effects of Adrenocorticotropic Hormone (ACTHAR Gel) on Recovery From Cognitive Relapses in Multiple Sclerosis</td>
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<td>Aug 2016</td>
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<td>NCT01386554a</td>
<td>A Randomized, Placebo-Controlled, Parallel-Group, Double-Blind Study of H.P. Acthar Gel (Acthar) in Treatment-Resistant Subjects With Persistent Proteinuria and Nephrotic Syndrome Due To Idiopathic Membranous Nephropathy (iMNP)</td>
<td>60</td>
<td>Dec 2016</td>
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<td>NCT02132195a</td>
<td>Adrenocorticotropic Hormone (ACTH) for Frequently Relapsing and Steroid Dependent Nephrotic Syndrome</td>
<td>60</td>
<td>Oct 2017</td>
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<tr>
<td>NCT02315872a</td>
<td>The Effect of ACTH (Acthar Gel) on Measures of Chronic Fatigue in Patients With Relapsing Multiple Sclerosis</td>
<td>90</td>
<td>Dec 2017</td>
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<tr>
<td>NCT01950234a</td>
<td>Treatment of Progressive Forms of Multiple Sclerosis With Pulsed ACTH (Acthar Gel)</td>
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<td>Dec 2018</td>
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<td>Unpublished</td>
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<tr>
<td>NCT01838174a</td>
<td>A Phase IV Trial of Neuroprotection With ACTH in Acute Optic Neuritis</td>
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<td>Apr 2015</td>
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<tr>
<td>NCT02113735a</td>
<td>A Randomized, Double-blind, Placebo-controlled, Parallel-Group Safety and Efficacy Study of H.P. Acthar Gel (Acthar) in Subjects With Acute Respiratory Distress Syndrome (ARDS)</td>
<td>0</td>
<td>Withdrawn before enrollment</td>
</tr>
</tbody>
</table>

NCT: national clinical trial.
* Denotes industry-sponsored or cosponsored trial.

Summary of Evidence

The evidence for repository corticotropin injection in patients with infantile spasms includes randomized controlled trials (RCTs) and a Cochrane systematic review. Relevant outcomes are symptoms and change in disease status. The overall quality of the studies is deemed poor, with fewer than half of the studies reporting method of randomization, relatively small numbers of patients, lack of differentiation between synthetic and natural forms of adrenocorticotropic hormone (ACTH), and various dosage and treatment regimens used in the studies. Most studies were done in comparison with either vigabatrin or prednisolone. Some of the RCTs, and the Cochrane review report improved response with repository corticotropin, but other RCTs do not. The most recent RCT published in 2014 reported that repository corticotropin was less effective than prednisolone, although clinical outcomes were not reported. The evidence is insufficient to determine the effects of the technology on health outcomes.

The evidence for repository corticotropin injection for patients with corticosteroid-responsive conditions (eg, rheumatoid arthritis, dermatomyositis, sarcoidosis, nephrotic syndrome, multiple sclerosis, serum sickness) includes RCTs and small cases series. Relevant outcomes are symptoms and change in disease status. Overall, more recent studies done in multiple sclerosis have demonstrated that intravenous corticosteroids are at least as effective, or more effective, than repository corticotropin. Studies done in nephrotic syndrome have been mainly small retrospective case studies, although ongoing studies are being conducted. The evidence is insufficient to determine the effects of the technology on health outcomes.
The evidence for repository corticotropin injection for diagnosing adrenal function includes no studies that report on diagnostic accuracy compared to ACTH. Relevant outcomes are test accuracy and validity and other test performance measures. The lack of published evidence precludes conclusions on the validity of using repository corticotropin as a diagnostic test for adrenal function. The evidence is insufficient to determine the effects of the technology on health outcomes.

The evidence for repository corticotropin injection for patients with non-corticosteroid-responsive conditions (e.g., tobacco cessation, childhood epilepsy, acute gout) includes 3 head-to-head trials identified for use in gout. Relevant outcomes are symptoms and change in disease status. The quality of these studies was deemed very low to moderate because there were no direct placebo-controlled trials and there were no clinically relevant differences found between drugs studied. The evidence is insufficient to determine the effects of the technology on health outcomes.

Clinical Input Received From Physician Specialty Societies and Academic Medical Centers
While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

In response to requests, input was received from 3 physician specialty societies and 1 academic medical center while this policy was under review for April 2010. In addition, unsolicited input was received from 1 foundation and 3 physicians. There was strong support for use of repository corticotropin in treatment of infantile spasms (West syndrome).

Practice Guidelines and Position Statements

American Academy of Neurology and Child Neurology Society
In 2012, the American Academy of Neurology and the Practice Committee of the Child Neurology Society published an updated evidence-based guideline on treatment of infantile spasms.\(^{13}\) The guideline included the following recommendations regarding use of ACTH:

- ACTH or vigabatrin may be useful for the short-term treatment of infantile spasms
- ACTH should be preferred over vigabatrin
- Hormonal therapy (ACTH or prednisolone) may be considered for treatment of infants with cryptogenic infantile spasms

American College of Rheumatology
In 2012, the American College of Rheumatology published guidelines on therapy and anti-inflammatory prophylaxis of acute gouty arthritis.\(^{14}\) The guideline committee did not reach a consensus on use of ACTH for patients with acute gout who are able to take medications orally. For patients unable to take oral medications, the committee agreed that subcutaneous synthetic ACTH was a reasonable alternative to oral prednisone or prednisolone therapy.
Infantile Spasms Working Group
In 2010, an industry-sponsored Infantile Spasms Working Group published a consensus report on diagnosis and treatment of infantile spasms.\(^{15}\) Regarding treatment, the report concluded: “At this time, ACTH and VGB (vigabatrin) are the only drugs with proven efficacy to suppress clinical spasms and abolish the hypsarrhythmic EEG [electroencephalogram] in a randomized clinical trial setting (Mackay et al., 2004) and thus remain first-line treatment.”

U.S. Preventive Services Task Force Recommendations
Not applicable.

Medicare National Coverage
There is no national coverage determination (NCD).

V. Definitions

N/A

VI. Benefit Variations

The existence of this medical policy does not mean that this service is a covered benefit under the member's contract. Benefit determinations should be based in all cases on the applicable contract language. Medical policies do not constitute a description of benefits. A member’s individual or group customer benefits govern which services are covered, which are excluded, and which are subject to benefit limits and which require preauthorization. Members and providers should consult the member’s benefit information or contact Capital for benefit information.

VII. Disclaimer

Capital’s medical policies are developed to assist in administering a member’s benefits, do not constitute medical advice and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member’s benefit information, the benefit information will govern. Capital considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.
VIII. CODING INFORMATION

Note: This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

Covered when medically necessary:

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<th>HCPSC Code</th>
<th>Description</th>
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<td>J0800</td>
<td>Injection, corticotropin, up to 40 units</td>
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<table>
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<tr>
<th>ICD-10-CM Diagnosis Code#</th>
<th>Description</th>
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<tbody>
<tr>
<td>G35</td>
<td>Multiple sclerosis</td>
</tr>
<tr>
<td>G40.821</td>
<td>Epileptic spasms, not intractable, with status epilepticus</td>
</tr>
<tr>
<td>G40.822</td>
<td>Epileptic spasms, not intractable, without status epilepticus</td>
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<td>G40.824</td>
<td>Epileptic spasms, intractable, without status epilepticus</td>
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</table>

*If applicable, please see Medicare LCD or NCD for additional covered diagnoses.

IX. REFERENCES


Other Sources:
Publication 100-02. Chapter 15. Section 50.4.2. Unlabeled Use of Drug Effective 10/01/03.
Publication 100-02. Chapter 15. Sections 50, 50.4.1, 50.4.3. Drugs and Biologicals.

X.  POLICY HISTORY

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<th>Policy Number</th>
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<tr>
<td>MP 2.162</td>
<td>CAC 7/26/11</td>
<td>New policy. Adopted BCBSA. Medically necessary for infantile spasms. Not medically necessary as treatment of corticosteroid-responsive conditions, unless there are medical contraindications or intolerance to corticosteroids that are not expected to occur with use of repository corticotropin injection. Codes reviewed 12/13/12</td>
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<td>CAC 7/30/13</td>
<td>Minor review. References updated. FEP variation revised to refer to the policy manual. Added criteria for treatment of infantile spasms. Added medically necessary indications for treatment of Multiple Sclerosis exacerbations. Policy statements changed to match pharmacy policy. Admin code review complete.</td>
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<td>Product variation section updated.</td>
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