CVS/caremark™

POLICY Document for HyQvia

The overall objective of this policy is to support the appropriate and cost effective use of the medication, specific to use of lower cost site of care and overall clinically appropriate use. This document provides specific information to each section of the overall policy.

Section 1: Site of Care
- Policy information specific to site of care (outpatient, hospital outpatient, home infusion)

Section 2: Clinical Criteria
- Policy information specific to the clinical appropriateness for the medication

Section 1: Site of Care

Site of Care Criteria
Administration of Subcutaneous HyQvia

POLICY

I. CRITERIA FOR APPROVAL FOR ADMINISTRATION IN OUTPATIENT HOSPITAL SETTING

This policy provides coverage for administration of HyQvia in an outpatient hospital setting for up to 2 doses when a member is new to therapy.

This policy provides coverage for administration of HyQvia in an outpatient hospital setting for a longer course of treatment when ANY of the following criteria are met:

A. The member has experienced an adverse reaction that did not respond to conventional interventions (eg, acetaminophen, steroids, diphenhydramine, fluids or other pre-medications) or a severe adverse event (anaphylaxis, anaphylactoid reactions, myocardial infarction, thromboembolism, or seizures) during or immediately after an infusion.
B. The member has developed anti-IgA antibodies which increases the risk for infusion related reactions.
C. The member is medically unstable (eg respiratory, cardiovascular, or renal conditions).
D. The member has significant behavioral issues and/or physical or cognitive impairment that would impact the safety of drug administration AND the patient does not have access to a caregiver.
E. Alternative infusion sites are not available.
F. The member is less than 21 years of age or 65 years of age or older.

For situations where administration of HyQvia does not meet the criteria for outpatient hospital infusion, coverage for HyQvia is provided when administered in alternative sites such as; physician office, home infusion or ambulatory care.

II. REQUIRED DOCUMENTATION

The following information is necessary to initiate the site of care prior authorization review (where applicable):

A. Medical records supporting the member has experienced an adverse reaction that did not respond to conventional interventions or a severe adverse event during or immediately after an infusion
B. Medical records supporting the member has developed anti-IgA antibodies
C. Medical records supporting the member is medically unstable

D. Medical records supporting the member has behavioral issues and/or physical or cognitive impairment and no access to a caregiver
E. Records supporting alternative infusion sites are not available

Section 2: Clinical Criteria

SPECIALTY GUIDELINE MANAGEMENT

Subcutaneous Immune Globulin (SCIG): Hizentra®, HyQvia®, Cutaquig® and Cuvitru™

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

A. **Cutaquig (Immune Globulin Subcutaneous [Human] - hipp, 16.5% Solution)**
Cutaquig is indicated as replacement therapy for primary humoral immunodeficiency (PI) in adults.

B. **Cuvitru (Immune Globulin Subcutaneous [Human], 20% Solution)**
Cuvitru is indicated as replacement therapy for primary humoral immunodeficiency in adult and pediatric patients two years of age and older.

C. **Hizentra (Immune Globulin Subcutaneous [Human], 20% Liquid)**
1. Hizentra is indicated for the treatment of primary immunodeficiency in adults and pediatric patients 2 years of age and older.

2. Hizentra is indicated for the treatment of adult patients with chronic inflammatory demyelinating polyneuropathy (CIDP) as maintenance therapy to prevent relapse of neuromuscular disability and impairment.

Limitations of Use:
Hizentra maintenance therapy in CIDP has been systematically studied for 6 months and for a further 12 months in a follow-up study. Maintenance therapy beyond these periods should be individualized based upon the patient's response and need for continued therapy.

D. **HyQvia (Immune Globulin Infusion 10% [Human] with Recombinant Human Hyaluronidase)**
HyQvia is indicated for the treatment of primary immunodeficiency in adults.

Limitation of use: Safety and efficacy of chronic use of recombinant human hyaluronidase in HyQvia have not been established in conditions other than primary immunodeficiency.

All other indications are considered experimental/investigational and are not a covered benefit.

II. REQUIRED DOCUMENTATION

The following information is necessary to initiate the prior authorization review (for primary immunodeficiency only):

A. Diagnostic test results (when applicable)
   1. Copy of laboratory report with serum immunoglobulin levels: IgG, IgA, IgM, and IgG subclasses
   2. Vaccine response to pneumococcal polysaccharide vaccine (post- vaccination *Streptococcus pneumoniae* antibody titers)
   3. Copy of laboratory report with lymphocyte subset enumeration by flow cytometry
   4. Pertinent genetic or molecular testing in members with a known genetic disorder

B. IgG trough level for those continuing with SCIG therapy

III. CRITERIA FOR INITIAL APPROVAL

A. Primary Immunodeficiency

Initial authorization of 12 months may be granted for members with any of the following diagnoses:

1. Severe combined immunodeficiency (SCID) or congenital agammaglobulinemia (eg, X-linked or autosomal recessive agammaglobulinemia):
   a. Diagnosis confirmed by genetic or molecular testing, or
   b. Pretreatment IgG level < 200 mg/dL, or
   c. Absence or very low number of T cells (CD3 T cells < 300/microliter) or the presence of maternal T cells in the circulation (SCID only)
2. Wiskott-Aldrich syndrome, DiGeorge syndrome, or ataxia-telangiectasia (or other non-SCID combined immunodeficiency):
   a. Diagnosis confirmed by genetic or molecular testing (if applicable), and
   b. History of recurrent bacterial infections (eg, pneumonia, otitis media, sinusitis, sepsis, gastrointestinal), and
   c. Impaired antibody response to pneumococcal polysaccharide vaccine (see Appendix)
3. Common variable immunodeficiency (CVID):
   a. Age 4 years or older
   b. Other causes of immune deficiency have been excluded (eg, drug induced, genetic disorders, infectious diseases such as HIV, malignancy)
   c. Pretreatment IgG level < 500 mg/dL or ≥ 2 SD below the mean for age
   d. History of recurrent bacterial infections
   e. Impaired antibody response to pneumococcal polysaccharide vaccine (see Appendix)
4. Hypogammaglobulinemia (unspecified), IgG subclass deficiency, selective IgA deficiency, selective IgM deficiency, or specific antibody deficiency:
   a. History of recurrent bacterial infections
   b. Impaired antibody response to pneumococcal polysaccharide vaccine (see Appendix)
   c. Any of the following pre-treatment laboratory findings:
      i. Hypogammaglobulinemia: IgG < 500 mg/dL or ≥ 2 SD below the mean for age
      ii. Selective IgA deficiency: IgA level < 7 mg/dL with normal IgG and IgM levels
      iii. Selective IgM deficiency: IgM level < 30 mg/dL with normal IgG and IgA levels
      iv. IgG subclass deficiency: IgG1, IgG2, or IgG3 ≥ 2 SD below mean for age assessed on at least 2 occasions; normal IgG (total) and IgM levels, normal/low IgA levels
      v. Specific antibody deficiency: normal IgG, IgA and IgM levels
5. Other predominant antibody deficiency disorders must meet a., b., and c.i. in section 4. above.
6. Other combined immunodeficiency must meet criteria in section 2. above.

B. Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) (Hizentra only)
Initial authorization of 3 months may be granted for the maintenance treatment of CIDP in members currently receiving intravenous immune globulin (IVIG) therapy.[3]

IV. CONTINUATION OF THERAPY

The following criteria apply to members who are currently receiving SCIG therapy through a paid pharmacy or medical benefit. All other members (including new members) must meet initial authorization criteria.

A. Primary Immunodeficiency
Authorization of 24 months may be granted when the following criteria are met:
1. A reduction in the frequency of bacterial infections has been demonstrated since initiation of SCIG therapy, AND
2. IgG trough levels are monitored at least yearly and maintained at or above the lower range of normal for age (when applicable for indication), OR
3. The prescriber will re-evaluate the dose of SCIG and consider a dose adjustment (when appropriate).

B. Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) (Hizentra only)
Authorization of 24 months may be granted when the following criteria are met:
1. Maintenance of response from previous IVIG therapy
2. SCIG is being used at the lowest effective dose

V. APPENDIX

Impaired Antibody Response to Pneumococcal Polysaccharide Vaccine
- Age 2 years and older: impaired antibody response demonstrated to vaccination with a pneumococcal polysaccharide vaccine
- Not established for children less than 2 years of age
- Excludes the therapy initiated in the hospital setting

REFERENCES:

SECTION 1
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SECTION 2
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3. Hizentra [package insert]. Kankakee, IL: CSL Behring LLC; March 2018.
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