**HyQvia**
*(Immune Globulin Infusion 10% [Human] with Recombinant Human Hyaluronidase)*

**Line(s) of Business:**
HMO; PPO; QUEST Integration

**Original Effective Date:**
05/21/1999
10/01/2015

**Current Effective Date:**
12/01/2017
05/01/2019

**POLICY**

**A. 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**
HyQvia is indicated for the treatment of primary immunodeficiency (PI) in adults. *This includes, but is not limited to, common variable immunodeficiency (CVID), X-linked agammaglobulinemia, congenital agammaglobulinemia, Wiskott-Aldrich syndrome, and severe combined immunodeficiencies.*

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.

**B. REQUIRED DOCUMENTATION**

The following information is necessary to initiate the prior authorization review:

- **Initial therapy**
  - Documentation supporting the member’s inability to tolerate intravenously administered immune globulin

- **For primary immunodeficiency, initial authorization**
  - Laboratory evidence of immunoglobulin deficiency (see Appendix)
  - Laboratory evidence of inability to mount an adequate response to inciting antigens (see Appendix)

- **For primary immunodeficiency, continuation of therapy**
  - Documentation supporting a clinical response to therapy (eg, reduction in bacterial infections)

**C. CRITERIA FOR APPROVAL**

Primary immunodeficiency (includes congenital agammaglobulinemia (X-linked agammaglobulinemia), hypogammaglobulinemia, common variable immunodeficiency, X-linked immunodeficiency with hyperimmunoglobulin M, severe combined immunodeficiency and Wiskott-Aldrich syndrome)
Initial authorization for 12 months may be granted for members who meet the following criteria:

1. Member is unable to tolerate intravenously administered immune globulin
2. Laboratory evidence of immunoglobulin deficiency (see Appendix)
3. Documented inability to mount an adequate response to inciting antigens (see Appendix)
4. Persistent and severe infections despite treatment with prophylactic antibiotics

D. CONTINUATION OF THERAPY

1. No previous authorization/precertification:
   All members (including new members and members currently receiving treatment without prior authorization) must meet criteria for initial approval in section C.
2. Reauthorization:
   Authorization of an additional 12 months may be granted to members requesting authorization for continuation of therapy if who are benefitting from HyQvia therapy (eg, reduction in bacterial infections) and were previously authorized by HMSA/CVS and member demonstrated a clinical response to therapy (eg, reduction in bacterial infections).

E. APPENDIX - Primary Immunodeficiency Syndromes.

The diagnosis of immunodeficiency and post immunization titers must be taken in context with the clinical presentation of the patient and may vary dependent on the type of vaccine given and the prior immunization history of the patient. The following parameters are examples of criteria for diagnosis of the primary immunodeficiency syndromes.

1. Laboratory evidence of immunoglobulin deficiency may include the following definitions:
   a. Agammaglobulinemia (total IgG less than 200 mg/dL)
   b. Persistent hypogammaglobulinemia (total IgG less than 400 mg/dL, or at least two standard deviations below normal, on at least two occasions)
   c. Absence of B lymphocytes

2. Inability to mount an adequate antibody response to inciting antigens may include the following definitions:
   a. Lack of appropriate rise in antibody titer following provocation with a polysaccharide antigen. For example, an adequate response to the pneumococcal vaccine may be defined as at least a 4-fold increase in titers for at least 50% of serotypes tested.
   b. Lack of appropriate rise in antibody titer following provocation with a protein antigen. For example, an adequate response to tetanus/diphtheria vaccine may be defined as less than a 4-fold rise in titers 3-4 weeks after vaccine administration.

F. DOSAGE AND ADMINISTRATION

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

G. ADMINISTRATIVE GUIDELINES

Precertification is required. Please refer to the HMSA medical policy web site for the fax form.

H. IMPORTANT REMINDER

The purpose of this Medical Policy is to provide a guide to coverage. This Medical Policy is not intended to dictate to providers how to practice medicine. Nothing in this Medical Policy is intended
to discourage or prohibit providing other medical advice or treatment deemed appropriate by the treating physician.

Benefit determinations are subject to applicable member contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control.

This Medical Policy has been developed through consideration of the medical necessity criteria under Hawaii’s Patients’ Bill of Rights and Responsibilities Act (Hawaii Revised Statutes §432E-1.4), generally accepted standards of medical practice and review of medical literature and government approval status. HMSA has determined that services not covered under this Medical Policy will not be medically necessary under Hawaii law in most cases. If a treating physician disagrees with HMSA/CVS’s determination as to medical necessity in a given case, the physician may request that CVS/caremarkHMSA reconsider the application of the medical necessity criteria to the case at issue in light of any supporting documentation.

I. REFERENCES

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