SCIG IMMUNE GLOBULIN
Cutaquig, Cuvitru, Hizentra, Hyqvia (subcutaneous immunoglobulin)

Pre - PA Allowance
None

Prior-Approval Requirements

Age Cuvitru and Hizentra 2 years and older
Cutaquig and Hyqvia 18 years and older

Diagnoses

Patient must have ONE of the following
1. Primary Immunodeficiency Disease (PID) with ONE of the following:
   a. Hypogammaglobulinemia, IgG subclass deficiency, selective IgA
deficiency, selective IgM deficiency, or specific antibody deficiency with
   ALL of the following:
      i. Documented history of recurrent bacterial and viral infections
      ii. Impaired antibody response to pneumococcal vaccine
      iii. ONE of the following pre-treatment laboratory findings:
         1) Hypogammaglobulinemia: IgG < 500 mg/dL or > 2 SD below
            the mean age
         2) Selective IgA deficiency: IgA level < 7 mg/dL with normal IgG
            and IgM levels
         3) Selective IgM deficiency: IgM level < 30 mg/dL with normal
            IgG and IgA levels
         4) IgG subclass deficiency: IgG1, IgG2, or IgG3 > 2 SD below
            the mean age assessed on at least 2 occasions; normal IgG
            (total) and IgM levels, normal/ low IgA levels
         5) Specific antibody deficiency: normal IgG, IgA and IgM levels
   b. SCID (severe combined immunodeficiency disease) or
      Agammaglobulinemia with ONE of the following
      i. Confirmed diagnosis by genetic or molecular testing
      ii. Pretreatment IgG level < 200 mg/dL
      iii. Absence or very low number of T cells (CD3 T cells < 300/microliter)
          or presence of maternal T cells in the circulation (SCID only)
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c. Wiskott-Aldrich syndrome, DiGeorge syndrome, or ataxia-telangiectasia (or other non SCID combined immunodeficiency) with ALL of the following:
   i. Confirmed diagnosis by genetic or molecular testing
   ii. Documented history of recurrent bacterial and viral infections
   iii. Impaired antibody response to pneumococcal vaccine

d. CVID (common variable Immunodeficiency disease) with ALL of the following:
   i. Documented history of recurrent bacterial and viral infections
   ii. Impaired antibody response to pneumococcal vaccine
   iii. Other causes of immune deficiency have been excluded (eg, drug induced, genetic disorders, infectious diseases such as HIV, malignancy)
   iv. Pretreatment IgG level < 500mg/dL or >2 SD below the mean for the age

Hizentra ONLY

2. Chronic inflammatory demyelinating polyneuropathy (CIDP)
   a. 18 years of age or older
   b. Previous treatment with immunoglobulin therapy (IVIG)
   c. Prescriber agrees to initiate Hizentra one week after the last infusion of IVIG
   d. Patient had significant improvement in disability and has maintained improvement while on previous immunoglobulin therapy (IVIG)

AND ALL of the following for BOTH indications:
   a. Patients or caregivers have been instructed on how to monitor for signs and symptoms of thrombosis when self-administering the medication
   b. NO dual therapy with other immune globulin medications

Prior - Approval Limits
Duration  12 months
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Prior – Approval *Renewal* Requirements

**Age**

- Cuvitru and Hizentra: 2 years and older
- Cutaquig and Hyqvia: 18 years and older

**Diagnoses**

Patient must have the *ONE* of following

1. Primary Immunodeficiency Disease (PID) with *ONE* of the following:
   a. Hypogammaglobulinemia, IgG subclass deficiency, selective IgA deficiency, selective IgM deficiency, or specific antibody deficiency
   b. SCID (severe combined immunodeficiency disease) or Agammaglobulinemia
   c. Wiskott-Aldrich syndrome, DiGeorge syndrome, or ataxia-telangiectasia (or other non SCID combined immunodeficiency)
   d. CVID (common variable Immunodeficiency disease)

Hizentra **ONLY**

2. Chronic inflammatory demyelinating polyneuropathy (CIDP)
   a. 18 years of age and older
   b. CIDP symptoms have remained stable or improved since changing from previous immunoglobulin therapy (intravenous immunoglobulin)
   c. Chronic stable patients have been tapered and/or treatment withdrawn to determine whether continued treatment is necessary

**AND ALL** of the following for **BOTH** indications:

a. Reduction in frequency of bacterial and viral infections has been documented since initiation
b. IgG trough levels are monitored at least yearly and maintained at or above the lower range of normal for age (when applicable for indication)
c. The prescriber will re-evaluate the dose of the SCIG and reconsider a dose adjustment
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d. Patients or caregivers have been instructed on how to monitor for signs and symptoms of thrombosis when self-administering the medication
e. NO dual therapy with other immune globulin medications

Prior – Approval Renewal Limits
Duration 12 months