BlueCross BlueShield
Federal Employee Program

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

Pre - PA Allowance
None

Prior-Approval Requirements

Age

2 years of age and older for **Cutaquig, Cuvitru, Hizentra** (PID), **Hyqvia** (PID), and **Xembify**
18 years of age and older for **Hizentra** (CIDP) and **Hyqvia** (CIDP)

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 $\geq$ 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 $\geq$ 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 <200mg/dL

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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)

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 and Hyqvia **ONLY**

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

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

a. Patients or caregivers have been instructed on how to monitor for signs and symptoms of thrombosis when self-administering the medication

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b. **NO** dual therapy with other immune globulin medications

Prior - Approval Limits

Duration 12 months

Prior – Approval *Renewal* Requirements

Age

2 years of age and older for **Cutaquig, Cuvitru, Hizentra** (PID), **Hyqvia** (PID), and **Xembify**
18 years of age and older for **Hizentra** (CIDP) and **Hyqvia** (CIDP)

Diagnoses

Patient must have **ONE** of the following:

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

AND ALL of the following:

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
c. The prescriber will re-evaluate the dose of the SCIG and reconsider a dose adjustment
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

Hizentra and Hyqvia **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. The prescriber will re-evaluate the dose of the SCIG and reconsider a dose adjustment
    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

Same as above