

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:
 - Hypogammaglobulinemia: IgG < 500 mg/dL or > 2 SD below the mean age
 - Selective IgA deficiency: IgA level < 7 mg/dL with normal IgG and IgM levels
 - Selective IgM deficiency: IgM level < 30 mg/dL with normal IgG and IgA levels
 - 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 <200mg/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)
- 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
 - 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



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 ataxiatelangiectasia (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