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CENTRAL HEALTH MEDICARE PLAN

Medical Policy

Subcutaneous immune globulins (SCIG) Hizentra®, Gammagard Liquid®, Gamunex®-C, Gammaked®, Hyqvia®, Cuvitru®, Cutaquig®	
MEDICAL POLICY NUMBER	MED_Clin_Ops_080
CURRENT VERSION EFFECTIVE DATE	January 1, 2024
APPLICABLE PRODUCT AND MARKET	*Individual Family Plan:* All Plans *Small Group*: All Plans *Medicare Advantage:* All Plans

Brand New Day/Central Health Medicare Plan develops policies and makes coverage determinations using credible scientific evidence including but not limited to MCG™ Health Guidelines, the ASAM Criteria™, and other third party sources, such as peer-reviewed medical literature generally recognized by the relevant medical community, physician specialty society recommendations, and expert opinion as relevant to supplement those sources. Brand New Day/Central Health Medicare Plan Medical Policies, MCG™ Guidelines, and the ASAM Criteria™ are not intended to be used without the independent clinical judgment of a qualified health care provider considering the individual circumstances of each member's case. The treating health care providers are solely responsible for diagnosis, treatment, and medical advice. Members may contact Brand New Day/Central Health Medicare Plan Customer Service at the phone number listed on their member identification card to discuss their benefits more specifically. Providers with questions about this Brand New Day/Central Health Medicare Plan Medical Policy may contact the Health Plan. Brand New Day/Central Health Medicare Plan policies and practices are compliant with federal and state requirements, including mental health parity laws.

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PURPOSE

The purpose of this policy is to establish the clinical review criteria that support the determination of medical necessity for Subcutaneous immune globulin (SCIG) therapy.

POLICY

Prior Authorization and Medical Review is required.

Coverage will be provided for 6 months and may be renewed for 12 month intervals thereafter.

Dosing Limitation:

Drug Name	Billable units/28 days
Hizentra	960 (PID)
Gamunex-C & Gammaked	1840 (CIDP)
	192
Gammagard liquid	192
HyQvia	690
Cuvitru	920
Cutaquig	N/A (96g/28 days)
Xembify	960

***Xembify** -Prior to switching to Xembify, obtain patient's serum IgG trough level to guide subsequent dose adjustment. Switching from immune globulin intravenous (human), 10% (IVIG) to XEMBIFY: calculate the dose by using a dose adjustment factor. Xembify is to be given one week after the last IVIGinfusion.*

Initial

Primary immunodeficiency (PID)/Wiskott -Aldrich syndrome
Such as: x-linked agammaglobulinemia, common variable immunodeficiency, transient hypogammaglobulinemia of infancy, IgG subclass deficiency with or without IgA deficiency, antibody deficiency with near normal immunoglobulin levels) and combined deficiencies (severe combined immunodeficiencies, ataxia-telangiectasia, x-linked lymphoproliferative syndrome) ***[list not all inclusive]***

A. For HyQvia and Cutaquig: Patient must be 18 years of age or older;
   For Gammagard Liquid, Gamunex-C, Gammaked, Cuvitru, Xembify: Patient must be 2 years of age or older; **AND**
B. Patient has a documented IgG level less than 200 mg/dL **OR** both of the following:
   - **a.** Patient has a history of multiple hard to treat infections as indicated by at least one of the following:
     - **i.** Four or more ear infections within 1 year
     - **ii.** Two or more serious sinus infections within 1 year
     - **iii.** Two or more months of antibiotics with little effect
     - **iv.** Two or more pneumonias within 1 year
     - **v.** Recurrent or deep skin abscesses
     - **vi.** Need for intravenous antibiotics to clear infections
     - **vii.** Two or more deep-seated infections including septicemia; **AND**
   - **b.** Patient has a deficiency in producing antibodies in response to vaccination; **AND**
     - **i.** Titers were drawn before challenging with vaccination; **AND**
     - **ii.** Titers were drawn between 4 and 8 weeks of vaccination.

Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) [Hizentra ONLY]
A. Patient is 18 years of age or older; **AND**
B. Requesting provider has assessed baseline disease severity utilizing an objective measure/tool; **AND**

a. Hizentra will be used as initial maintenance therapy for prevention of disease relapses after treatment and stabilization with intravenous immunoglobulin (IVIG)§; **OR**
b. Hizentra will be used for re-initiation of maintenance therapy after experiencing a relapse and requiring re- induction therapy with IVIG* (*see Hizentra Renewal Criteria).

§ Initial IVIG criteria used for determination of coverage: *(Reference Use Only)*

- Patient's disease course is progressive or relapsing and remitting for 2 months or longer; AND
- Patient has abnormal or absent deep tendon reflexes in upper or lower limbs; AND
- Electrodiagnostic testing indicating demyelination:
  - Partial motor conduction block in at least two motor nerves or in 1 nerve plus one other demyelination criterion listed here in at least 1 other nerve; OR
  - Distal CMAP duration increase in at least 1 nerve plus one other demyelination criterion listed here in at least 1 other nerve; OR
  - Abnormal temporal dispersion conduction must be present in at least 2 motor nerves; OR
  - Reduced conduction velocity in at least 2 motor nerves; OR
  - Prolonged distal motor latency in at least 2 motor nerves; OR
  - Absent F wave in at least two motor nerves plus one other demyelination criterion listed here in at least 1 other nerve; OR
  - Prolonged F wave latency in at least 2 motor nerves; AND
- Cerebrospinal fluid analysis indicates the following:
  - CSF white cell count of <10 cells/mm^3; AND
  - CSF protein is elevated; AND
- Patient is refractory or intolerant to corticosteroids (e.g., prednisolone, prednisone, etc.) given in therapeutic doses over at least three months; AND
- Baseline in strength/weakness has been documented using an objective clinical measuring tool (e.g., INCAT, Medical Research Council (MRC) muscle strength, 6-MWT, Rankin, Modified Rankin,etc.)

Renewal

Primary immunodeficiency (PID)/Wiskott -Aldrich syndrome

A. Documentation of disease response as evidenced by one or more of the following:
   a. Decrease in the frequency of infection
   b. Decrease in the severity of infection

Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)

A. Renewals will be authorized for patients who have demonstrated a beneficial clinical response to maintenance therapy with subcutaneous immune globulin therapy.
B. Hizentra ONLY:
   a. Patient is re-initiating maintenance therapy; **AND**

b. Patient has improved and stabilized on IVIG treatment before re-initiating Hizentra.

LIMITATIONS/EXCLUSIONS

1. Any indication other than those listed above due to insufficient evidence of therapeutic value
2. Hizentra –
   a. History of anaphylactic or severe systemic reaction to human immune globulin or inactive ingredients, such as polysorbate 80.
   b. Hyperprolinemia Type I or II because it contains L-proline as a stabilizer.
   c. IgA-deficiency with antibodies against IgA and a history of hypersensitivity.
3. Gammagard Liquid, Gamunex-C, Gammaked, Cuvitru -
   a. Patients who have a history of anaphylactic or severe systemic hypersensitivity reactions to administration of human immune globulin.
   b. IgA-deficient patients with antibodies to IgA and a history of hypersensitivity.
4. Hyqvia –
   a. Patients who have had a history of anaphylactic or severe systemic reactions to the administration of IgG.
   b. IgA deficient patients with antibodies to IgA and a history of hypersensitivity.
   c. Patients with known systemic hypersensitivity to hyaluronidase including Recombinant Human Hyaluronidase of HYQVIA.
   d. Patients with known systemic hypersensitivity to human albumin (in the hyaluronidase solution)].

CODING

Applicable Procedure Code	
J1559	Injection, immune globulin (Hizentra), 100 mg
J1561	Injection, immune globulin, (Gamunex-C/Gammaked), non-lyophilized (e.g. liquid), 500 mg
J1569	Injection, immune globulin, (Gammagard liquid), non-lyophilized, (e.g. liquid), 500 mg
J1575	Injection, immune globulin/hyaluronidase, (HyQvia), 100 mg immune globulin
J1555	Injection, immune globulin (Cuvitru), 100 mg
J1558	Injection, immune globulin, 100 mg (Xembify)
J3590	Unclassified biologic, when used for Cutaquig

Applicable NDCs			
Drug Name	**NDC**	**IgG (grams)**	**Volume (mL)**
Hizentra 20%	44206-0451-01	1	5
	44206-0452-02	2	10
	44206-0454-04	4	20
	44206-0455-10	10	50
Gammaked 10%	76125-0900-01	1	10
	76125-0900-25	2.5	25
	76125-0900-50	5	50
	76125-0900-10	10	100

	76125-0900-20	20	200
Gamunex-C 10%	13533-0800-12	1	10
	13533-0800-15	2.5	25
	13533-0800-20	5	50
	13533-0800-71	10	100
	13533-0800-24	20	200
	13533-0800-40	40	400
	00944-2700-02	1	10

Gammagard Liquid 10%	00944-2700-03	2.5	25
	00944-2700-04	5	50
	00944-2700-05	10	100
	00944-2700-06	20	200
	00944-2700-07	30	300
HyQvia 10% (with Recombinant Human Hyaluronidase 160 U/mL)	00944-2510-02	2.5	25
	00944-2511-02	5	50
	00944-2512-02	10	100
	00944-2513-02	20	200
	00944-2514-02	30	300
Cuvitru 20%	00944-2850-01	1	5
	00944-2850-03	2	10
	00944-2850-05	4	20
	00944-2850-07	8	40
Cutaquig 16.5%	68892-0810-01	1	6
	68892-0810-02	1.65	10
	68892-0810-03	2	12
	68892-0810-04	3.3	20
	68892-0810-05	4	24
	68892-0810-06	8	48
Xembify	13533-0810-05	1	5
	13533-0810-06	1	5
	13533-0810-10	2	10
	13533-0810-11	2	10
	13533-0810-20	4	20
	13533-0810-21	4	20
	13533-0810-50	10	50
	13533-0810-51	10	50

Applicable ICD-10 Codes	
B20	Human immunodeficiency virus [HIV] disease
D80.0	Hereditary hypogammaglobulinemia
D80.1	Nonfamilial hypogammaglobulinemia
D80.2	Selective deficiency of immunoglobulin A [IgA]
D80.3	Selective deficiency of immunoglobulin G [IgG] subclasses
D80.4	Selective deficiency of immunoglobulin M [IgM]
D80.5	Immunodeficiency with increased immunoglobulin M [IgM]
D80.7	Transient hypogammaglobulinemia of infancy
D81.0	Severe combined immunodeficiency [SCID] with reticular dysgenesis
D81.1	Severe combined immunodeficiency [SCID] with low T- and B-cell numbers
D81.2	Severe combined immunodeficiency [SCID] with low or normal B-cell numbers
D81.6	Major histocompatibility complex class I deficiency
D81.7	Major histocompatibility complex class II deficiency
D81.89	Other combined immunodeficiencies
D81.9	Combined immunodeficiency, unspecified
D82.0	Wiskott-Aldrich syndrome
D83.0	Common variable immunodeficiency with predominant abnormalities of B-cell numbers and function
D83.2	Common variable immunodeficiency with autoantibodies to B- or T-cells
D83.8	Other common variable immunodeficiencies
D83.9	Common variable immunodeficiency, unspecified
G61.81	Chronic inflammatory demyelinating polyneuritis
G61.89	Other inflammatory polyneuropathies
G62.89	Other specified polyneuropathies

EVIDENCE BASED REFERENCES

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POLICY HISTORY

Original Effective Date	11/1/2021
Revised Date	February 2, 2022 – Annual Review and approval (no policy revisions made) March 1, 2023 – Adopted by MA UM Committee (no policy revisions made) January 1, 2024 - Updated to Brand New Day/Central Health Medicare Plan (no policy revisions made)
P&T Committee Endorsement	2/22/2022