

PHARMACY PRE-AUTHORIZATION CRITERIA



DRUG (S)	SCIG: Hizentra [®] , Gammagard Liquid [®] , Gamunex [®] -C, Gammaked [®] , Hyqvia, Cuvitru, Xembify (immune globulin SQ)
POLICY #	
INDICATIONS	<p>Subcutaneous Immune Globulins are FDA-Approved for the following indications:</p> <ul style="list-style-type: none"> • Primary immunodeficiency (PID)/Wiskott -Aldrich syndrome • Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)
CRITERIA	<p><u>Initial approval criteria:</u></p> <p>SCIG may be considered medically necessary if one of the below conditions are met AND use is consistent with the medical necessity criteria that follows:</p> <div style="border: 1px solid black; padding: 10px; margin: 10px 0;"> <ul style="list-style-type: none"> • The first dose may be given at the facility of choice by the physician; all subsequent doses will be given by home infusion coordinated by ConnectiCare’s preferred vendors • ConnectiCare’s preferred site of care for this medication is home infusion. Clinical rationale and documentation must be provided for review for exceptions. The following are considerations for services outside the home: <ul style="list-style-type: none"> ○ Documented history of a severe reaction to this medication or any constituent of it. ○ Severe reaction is defined as anaphylactic reaction. ○ The patient should have a history of reactions and not be based on the potential of the medication to induce such reactions. ○ Documented intolerance to this medication requiring constant telemetry monitoring of vitals. ○ Unsafe home environment. ○ No access to 911 services. ○ Documented presence of IGA auto antibodies. </div> <p>Coverage is provided in the following conditions:</p> <ul style="list-style-type: none"> • Baseline values for BUN and serum creatinine obtained within 30 days of request; AND <p>Primary immunodeficiency (PID)/Wiskott - Aldrich syndrome †</p> <p>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)</p>

DRUG (S)	<p>SCIG: Hizentra[®], Gammagard Liquid[®], Gamunex[®]-C, Gammaked[®], Hyqvia, Cuvitru, Xembify (immune globulin SQ)</p>
	<p>[list not all inclusive]</p> <ul style="list-style-type: none"> • For HyQvia ONLY: Patient must be ≥ 18 years old; AND • Patient’s IgG level is <200 OR both of the following <ul style="list-style-type: none"> ○ Patient has a history of multiple hard to treat infections as indicated by at least one of the following: <ul style="list-style-type: none"> – Four or more ear infections within 1 year – Two or more serious sinus infections within 1 year – Two or more months of antibiotics with little effect – Two or more pneumonias within 1 year – Recurrent or deep skin abscesses – Need for intravenous antibiotics to clear infections – Two or more deep-seated infections including septicemia; AND ○ The patient has a deficiency in producing antibodies in response to vaccination; AND <ul style="list-style-type: none"> ▪ Titers were drawn before challenging with vaccination; AND ▪ Titers were drawn between 4 and 8 weeks of vaccination <p>† FDA Approved Indication(s)</p> <p>OR</p> <p>Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)</p> <ul style="list-style-type: none"> • Patient must be ≥ 18 years old; AND • Physician has assessed baseline disease severity utilizing an objective measure/tool; AND <ul style="list-style-type: none"> ○ Used as initial maintenance therapy for prevention of disease relapses after treatment and stabilization with intravenous immunoglobulin (IVIG); OR ○ Used for re-initiation of maintenance therapy after experiencing a relapse and requiring re-induction therapy with IVIG (see Section IV for criteria)

<p>DRUG (S)</p>	<p>SCIG: Hizentra[®], Gammagard Liquid[®], Gamunex[®]-C, Gammaked[®], Hyqvia, Cuvitru, Xembify (immune globulin SQ)</p>
	<p><u>Renewal Criteria:</u></p> <p>Coverage can be renewed for 1 year based upon the following criteria:</p> <ul style="list-style-type: none"> • Patient continues to meet criteria identified above; AND • Absence of unacceptable toxicity from the drug; AND • BUN and serum creatinine obtained within the last 6 months and the concentration and rate of infusion adjusted accordingly; AND <p>Primary immunodeficiency (PID)/Wiskott-Aldrich syndrome</p> <ul style="list-style-type: none"> • Disease response as evidenced by one or more of the following: <ul style="list-style-type: none"> ○ Decrease in the frequency of infection ○ Decrease in the severity of infection <p>Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)</p> <ul style="list-style-type: none"> • Renewals will be authorized for patients that have demonstrated a beneficial clinical response to maintenance therapy, without relapses, based on an objective clinical measuring tool; OR • Patient is re-initiating maintenance therapy after experiencing a relapse while on Hizentra; AND <ul style="list-style-type: none"> ○ Patient improved and stabilized on IVIG treatment; AND ○ Patient was NOT receiving maximum dosing of Hizentra prior relapse

PHARMACY PRE-AUTHORIZATION CRITERIA



DRUG (S)	SCIG: Hizentra [®] , Gammagard Liquid [®] , Gamunex [®] -C, Gammaked [®] , Hyqvia, Cuvitru, Xembify (immune globulin SQ)																
DOSAGE/ADMIN	<p>Dosing should be calculated using adjusted body weight if one or more of the following criteria are met:</p> <ul style="list-style-type: none"> • Patient’s body mass index (BMI) is 30 kg/m² or more; OR • Patient’s actual body weight is 20% higher than his or her ideal body weight (IBW) <p>Use the following dosing formulas to calculate the adjusted body weight (round dose to nearest 5 gram increment in adult patients):</p> <table border="1" data-bbox="472 909 1395 1167"> <thead> <tr> <th colspan="2">Dosing formulas</th> </tr> </thead> <tbody> <tr> <td>BMI</td> <td>$703 \times (\text{weight in pounds} / \text{height in inches}^2)$</td> </tr> <tr> <td>IBW(kg) for males</td> <td>$50 + [2.3 (\text{height in inches} - 60)]$</td> </tr> <tr> <td>IBW(kg) for females</td> <td>$45.5 + [2.3 \times (\text{height in inches} - 60)]$</td> </tr> <tr> <td>Adjusted body weight</td> <td>$IBW + 0.5 (\text{actual body weight} - IBW)$</td> </tr> </tbody> </table> <p>This information is not meant to replace clinical decision making when initiating or modifying medication therapy and should only be used as a guide. Patient-specific variables should be taken into account.</p> <table border="1" data-bbox="365 1339 1515 1858"> <thead> <tr> <th>Indication</th> <th>Dose</th> </tr> </thead> <tbody> <tr> <td rowspan="3">Primary immune deficiency including Wiskott-Aldrich Syndrome</td> <td> <u>Hizentra:</u> <ul style="list-style-type: none"> ▪ Weekly dose: $1.37 \times (\text{previous IVIG dose(g)} / \text{number of weeks between IVIG doses})$ ▪ Biweekly dose: twice the weekly dose (using calculation above) </td> </tr> <tr> <td> <u>Gamunex-C/Gammaked/Gammagard Liquid:</u> <ul style="list-style-type: none"> ▪ Weekly dose: $1.37 \times (\text{previous IVIG dose(g)} / \text{number of weeks between IVIG doses})$ </td> </tr> <tr> <td> <u>HyQvia:</u> <ul style="list-style-type: none"> ▪ Naïve to IgG or switching from SCIG: 300 to 600 mg/kg at 3 to 4 week intervals after initial ramp-up* ▪ Switching from IGIV: use the same dose and frequency as the previous IV </td> </tr> </tbody> </table>	Dosing formulas		BMI	$703 \times (\text{weight in pounds} / \text{height in inches}^2)$	IBW(kg) for males	$50 + [2.3 (\text{height in inches} - 60)]$	IBW(kg) for females	$45.5 + [2.3 \times (\text{height in inches} - 60)]$	Adjusted body weight	$IBW + 0.5 (\text{actual body weight} - IBW)$	Indication	Dose	Primary immune deficiency including Wiskott-Aldrich Syndrome	<u>Hizentra:</u> <ul style="list-style-type: none"> ▪ Weekly dose: $1.37 \times (\text{previous IVIG dose(g)} / \text{number of weeks between IVIG doses})$ ▪ Biweekly dose: twice the weekly dose (using calculation above) 	<u>Gamunex-C/Gammaked/Gammagard Liquid:</u> <ul style="list-style-type: none"> ▪ Weekly dose: $1.37 \times (\text{previous IVIG dose(g)} / \text{number of weeks between IVIG doses})$ 	<u>HyQvia:</u> <ul style="list-style-type: none"> ▪ Naïve to IgG or switching from SCIG: 300 to 600 mg/kg at 3 to 4 week intervals after initial ramp-up* ▪ Switching from IGIV: use the same dose and frequency as the previous IV
Dosing formulas																	
BMI	$703 \times (\text{weight in pounds} / \text{height in inches}^2)$																
IBW(kg) for males	$50 + [2.3 (\text{height in inches} - 60)]$																
IBW(kg) for females	$45.5 + [2.3 \times (\text{height in inches} - 60)]$																
Adjusted body weight	$IBW + 0.5 (\text{actual body weight} - IBW)$																
Indication	Dose																
Primary immune deficiency including Wiskott-Aldrich Syndrome	<u>Hizentra:</u> <ul style="list-style-type: none"> ▪ Weekly dose: $1.37 \times (\text{previous IVIG dose(g)} / \text{number of weeks between IVIG doses})$ ▪ Biweekly dose: twice the weekly dose (using calculation above) 																
	<u>Gamunex-C/Gammaked/Gammagard Liquid:</u> <ul style="list-style-type: none"> ▪ Weekly dose: $1.37 \times (\text{previous IVIG dose(g)} / \text{number of weeks between IVIG doses})$ 																
	<u>HyQvia:</u> <ul style="list-style-type: none"> ▪ Naïve to IgG or switching from SCIG: 300 to 600 mg/kg at 3 to 4 week intervals after initial ramp-up* ▪ Switching from IGIV: use the same dose and frequency as the previous IV 																

DRUG (S) SCIG: Hizentra®, Gammagard Liquid®, Gamunex®-C, Gammaked®, HyQvia, Cuvitru, Xembify (immune globulin SQ)

	treatment after initial ramp-up*
	<p><u>Cuvitru:</u></p> <ul style="list-style-type: none"> ▪ Switching from IVIG or HyQvia: <ul style="list-style-type: none"> ○ Weekly dose: 1.30*(previous IVIG or HyQvia dose (g)/number of weeks between IVIG or HyQvia doses) ○ May be administered from daily up to every two weeks (biweekly) ○ Biweekly dose: twice the weekly dose (using calculation above) ○ Frequent dosing (2-7 times per week): divide the calculated weekly dose by the desired number of times per week ▪ Switching from SCIG <ul style="list-style-type: none"> ○ Weekly dose (in grams) should be same as the weekly dose of prior SCIG treatment (in grams) ○ Biweekly dose: multiply the calculated weekly dose by 2 ○ Frequent dosing (2-7 times per week): divide the calculated weekly dose by the desired number of times per week

Dosing for immunoglobulin products is highly variable depending on numerous patient specific factors, indication(s), and the specific product selected. For specific dosing regimens refer to current prescribing literature.

*HyQvia initial treatment interval/dosage ramp-up schedule

Week	Infusion Number	3-week treatment interval	4-week treatment interval
1	1 st infusion	Dose in Grams X 0.33	Dose in Grams X 0.25
2	2 nd infusion	Dose in Grams X 0.67	Dose in Grams X 0.50
4	3 rd infusion	Total Dose in Grams	Dose in Grams X 0.75
7	4 th infusion	N/A	Total Dose in Grams

LIMITATIONS Initial coverage will be provided for 6 months and may be renewed annually thereafter

A. Quantity Limit (max daily dose) [Pharmacy Benefit]:

Drug Name	Dose/ week	Dose/28 days
Hizentra	24 g	96 g
Gamunex-C & Gammaked	24 g	96 g
Gammagard liquid	24 g	96 g
HyQvia	17.5 g	69 g
Cuvitru	23 g	92 g

PHARMACY PRE-AUTHORIZATION CRITERIA



DRUG (S)	SCIG: Hizentra®, Gammagard Liquid®, Gamunex®-C, Gammaked®, Hyqvia, Cuvitru, Xembify (immune globulin SQ)
----------	---

B. Max Units (per dose and over time) [Medical Benefit]:

Drug Name	Billable units/28 days
Hizentra	960
Gamunex-C & Gammaked	192
Gammagard liquid	192
HyQvia	690
Cuvitru (J3590)	920
Cuvitru (90284)	920
Xembify	N/A (96 gm)

***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 IVIG infusion.

Billing Code/Availability Information

J-Code & NDC:

Drug Name	Manufacturer	J Code	1 Billable unit	NDC	IgG (grams)	Volume (mL)
Hizentra 20%	CSL Behring AG	J1559 – Injection, immune globulin (Hizentra), 100 mg	100 mg	44206-0451-01	1	5
				44206-0451-02	2	10
				44206-0451-04	4	20
				44206-0451-10	10	50
Gammaked 10%	Kedron Biopharma, Inc.	J1561 Injection, immune globulin, (Gamunex-C/Gammaked), non-lyophilized (e.g. liquid), 500 mg	500 mg	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%	Grifols Therapeutics	J1561 – Injection, immune globulin, (Gamunex-C/Gammaked), non-	500 mg	13533-0800-12	1	10
				13533-0800-15	2.5	25
				13533-0800-20	5	50

PHARMACY PRE-AUTHORIZATION CRITERIA



DRUG (S)	SCIG: Hizentra[®], Gammagard Liquid[®], Gamunex[®]-C, Gammaked[®], Hyqvia, Cuvitru, Xembify (immune globulin SQ)						
DRUG (S)			lyophilized (e.g. liquid), 500 mg		13533-0800-71	10	100
					13533-0800-24	20	200
					13533-0800-40	40	400
	Gammagard Liquid 10%	Baxter Healthcare Corporation	J1569 – Injection, immune globulin, (Gammagard liquid), non-lyophilized, (e.g. liquid), 500 mg	500 mg	00944-2700-02	1	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)	Baxter Healthcare Corporation	J1575 – Injection, immune globulin/hyaluronidase, (Hyqvia), 100 mg immune globulin	100 mg	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%	Baxalta US Inc.	J3590 – unclassified biologic	N/A	00944-2850-01	1	5
					00944-2850-03	2	10
			90284 – immune globulin (SClg), human, for use in subcutaneous infusions	100 mg	00944-2850-05	4	20
					00944-2850-07	8	40
	Xembify	GRIFOLS USA	J3590 – unclassified biologic	N/A	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	

DRUG (S)	SCIG: Hizentra[®], Gammagard Liquid[®], Gamunex[®]-C, Gammaked[®], Hyqvia, Cuvitru, Xembify (immune globulin SQ)
REFERENCES	<ol style="list-style-type: none"> 1. Hizentra [package insert]. Bern, Switzerland; CSL Behring AG; October 2016. Accessed August 2017. 2. HyQvia [package insert]. Westlake Village, CA; Baxter Healthcare Corporation; September 2016. Accessed August 2017. 3. Cuvitru [package insert]. Westlake Village, CA; Baxalta US Inc.; September 2016. Accessed August 2017. 4. Gammagard Liquid [package insert]. Westlake Village, CA; Baxter Healthcare Corporation; June 2016. Accessed August 2017. 5. Gamunex[®]-C [package insert]. Research Triangle, NC; Grifols Therapeutics, Inc.; September 2016. Accessed August 2017. 6. Gammaked[™] [package insert]. Research Triangle, NC; Grifols Therapeutics, Inc.; September 2016. Accessed August 2017. 7. Jeffrey Modell Foundation Medical Advisory Board, 2013. 10 Warning Signs of Primary Immunodeficiency. Jeffrey Modell Foundation, New York, NY 8. Orange J, Hossny E, Weiler C, et al. Use of intravenous immunoglobulin in human disease: A review of evidence by members of the Primary Immunodeficiency Committee of the American Academy of Allergy, Asthma and Immunology. <i>J Allergy Clin Immunol</i> 2006;117(4 Suppl): S525-53. 9. Orange JS, Ballou M, Stiehm, et al. Use and interpretation of diagnostic vaccination in primary immunodeficiency: A working group report of the Basic and Clinical Immunology Interest Section of the American Academy of Allergy, Asthma & Immunology. <i>J Allergy Clin Immunol</i> Vol 130 (3). 10. Bonilla FA, Khan DA, Ballas ZK, et al. Practice Parameter for the diagnosis and management of primary immunodeficiency. <i>J Allergy Clin Immunol</i> 2015 Nov;136(5):1186-205.e1-78. 11. Emerson GG, Herndon CN, Sreih AG. Thrombotic complications after intravenous immunoglobulin therapy in two patients. <i>Pharmacotherapy</i>. 2002;22:1638-1641. 12. Department of Health (London). Clinical Guidelines for Immunoglobulin Use: Update to Second Edition. August, 2011. 13. Provan, Drew, et al. "Clinical guidelines for immunoglobulin use." Department of Health Publication, London (2008). 14. Dantal J. Intravenous Immunoglobulins: In-Depth Review of Excipients and Acute Kidney Injury Risk. <i>Am J Nephrol</i> 2013;38:275-284. 15. Immune Deficiency Foundation. Diagnostic & Clinical Care Guidelines for Primary Immunodeficiency Diseases. 3rd Ed. 2015. Avail at: https://primaryimmune.org/sites/default/files/publications/2015-Diagnostic-and-Clinical-Care-Guidelines-for-PI_1.pdf.

<p>DRUG (S)</p>	<p>SCIG: Hizentra[®], Gammagard Liquid[®], Gamunex[®]-C, Gammaked[®], Hyqvia, Cuvitru, Xembify (immune globulin SQ)</p>																																										
	<p>16. First Coast Service Options, Inc. Local Coverage Determination (LCD): Intravenous Immune Globulin (L34007). Centers for Medicare & Medicaid Services, Inc. Updated on 1/3/2017 with effective date 1/17/2017. Accessed August 2017.</p> <p>17. Wisconsin Physicians Service Insurance Corporation. Local Coverage Determination (LCD): Immune Globulins (L34771). Centers for Medicare & Medicaid Services, Inc. Updated on 6/20/2017 with effective date 7/1/2017. Accessed August 2017.</p> <p>18. XEMBIFY(R) subcutaneous injection, immune globulin human-klhw subcutaneous injection. Grifols Therapeutics LLC (per FDA), Research Triangle Park, NC, 2019.</p>																																										
<p>APPENDIX 1</p>	<p>Covered Diagnosis Codes</p> <table border="0"> <thead> <tr> <th data-bbox="370 961 456 989">ICD-10</th> <th data-bbox="529 961 756 989">ICD-10 Description</th> </tr> </thead> <tbody> <tr> <td data-bbox="370 999 418 1026">B20</td> <td data-bbox="529 999 1065 1026">Human immunodeficiency virus [HIV] disease</td> </tr> <tr> <td data-bbox="370 1037 444 1064">D80.0</td> <td data-bbox="529 1037 964 1064">Hereditary hypogammaglobulinemia</td> </tr> <tr> <td data-bbox="370 1075 444 1102">D80.1</td> <td data-bbox="529 1075 976 1102">Nonfamilial hypogammaglobulinemia</td> </tr> <tr> <td data-bbox="370 1113 444 1140">D80.2</td> <td data-bbox="529 1113 1070 1140">Selective deficiency of immunoglobulin A [IgA]</td> </tr> <tr> <td data-bbox="370 1150 444 1178">D80.3</td> <td data-bbox="529 1150 1211 1178">Selective deficiency of immunoglobulin G [IgG] subclasses</td> </tr> <tr> <td data-bbox="370 1188 444 1215">D80.4</td> <td data-bbox="529 1188 1094 1215">Selective deficiency of immunoglobulin M [IgM]</td> </tr> <tr> <td data-bbox="370 1226 444 1253">D80.5</td> <td data-bbox="529 1226 1230 1253">Immunodeficiency with increased immunoglobulin M [IgM]</td> </tr> <tr> <td data-bbox="370 1264 444 1291">D80.7</td> <td data-bbox="529 1264 1073 1291">Transient hypogammaglobulinemia of infancy</td> </tr> <tr> <td data-bbox="370 1302 444 1329">D81.0</td> <td data-bbox="529 1302 1338 1329">Severe combined immunodeficiency [SCID] with reticular dysgenesis</td> </tr> <tr> <td data-bbox="370 1339 444 1367">D81.1</td> <td data-bbox="529 1339 1414 1367">Severe combined immunodeficiency [SCID] with low T- and B-cell numbers</td> </tr> <tr> <td data-bbox="370 1377 444 1404">D81.2</td> <td data-bbox="529 1377 1458 1404">Severe combined immunodeficiency [SCID] with low or normal B-cell numbers</td> </tr> <tr> <td data-bbox="370 1415 444 1442">D81.6</td> <td data-bbox="529 1415 1130 1442">Major histocompatibility complex class I deficiency</td> </tr> <tr> <td data-bbox="370 1453 444 1480">D81.7</td> <td data-bbox="529 1453 1138 1480">Major histocompatibility complex class II deficiency</td> </tr> <tr> <td data-bbox="370 1491 444 1518">D81.89</td> <td data-bbox="529 1491 967 1518">Other combined immunodeficiencies</td> </tr> <tr> <td data-bbox="370 1528 444 1556">D81.9</td> <td data-bbox="529 1528 1024 1556">Combined immunodeficiency, unspecified</td> </tr> <tr> <td data-bbox="370 1566 444 1593">D82.0</td> <td data-bbox="529 1566 1463 1625">Wiskott-Aldrich syndrome Common variable immunodeficiency with predominant abnormalities of B-cell numbers and function</td> </tr> <tr> <td data-bbox="370 1635 444 1663">D83.0</td> <td data-bbox="529 1635 1386 1694">Common variable immunodeficiency with autoantibodies to B- or T-cells</td> </tr> <tr> <td data-bbox="370 1684 444 1711">D83.2</td> <td data-bbox="529 1684 1386 1711">Common variable immunodeficiency with autoantibodies to B- or T-cells</td> </tr> <tr> <td data-bbox="370 1722 444 1749">D83.8</td> <td data-bbox="529 1722 1057 1749">Other common variable immunodeficiencies</td> </tr> <tr> <td data-bbox="370 1759 444 1787">D83.9</td> <td data-bbox="529 1759 1114 1787">Common variable immunodeficiency, unspecified</td> </tr> </tbody> </table>	ICD-10	ICD-10 Description	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 Common variable immunodeficiency with predominant abnormalities of B-cell numbers and function	D83.0	Common variable immunodeficiency with autoantibodies to B- or T-cells	D83.2	Common variable immunodeficiency with autoantibodies to B- or T-cells	D83.8	Other common variable immunodeficiencies	D83.9	Common variable immunodeficiency, unspecified
ICD-10	ICD-10 Description																																										
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 Common variable immunodeficiency with predominant abnormalities of B-cell numbers and function																																										
D83.0	Common variable immunodeficiency with autoantibodies to B- or T-cells																																										
D83.2	Common variable immunodeficiency with autoantibodies to B- or T-cells																																										
D83.8	Other common variable immunodeficiencies																																										
D83.9	Common variable immunodeficiency, unspecified																																										

DRUG (S)	SCIG: Hizentra [®] , Gammagard Liquid [®] , Gamunex [®] -C, Gammaked [®] , Hyqvia, Cuvitru, Xembify (immune globulin SQ)
-----------------	---

APPENDIX 2	<p><u>Centers for Medicare and Medicaid Services (CMS)</u></p> <p>Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx. Additional indications may be covered at the discretion of the health plan.</p> <p><u>Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD):</u></p> <table border="1" style="width: 100%;"> <tr> <td style="width: 40%;">Jurisdiction(s): N</td> <td>NCD/LCD/Article Document (s): L34007 https://www.cms.gov/medicare-coverage-database/search/lcd-date-search.aspx?DocID=L34007&bc=gAAAAAAAAAAAAAA==</td> </tr> <tr> <td>Jurisdiction(s): 5,8</td> <td>NCD/LCD/Article Document (s): L34771 https://www.cms.gov/medicare-coverage-database/search/lcd-date-search.aspx?DocID=L34771&bc=gAAAAAAAAAAAAAA==</td> </tr> </table> <p><u>Medicare Part B Administrative Contractor (MAC) Jurisdictions:</u></p> <table border="1" style="width: 100%;"> <thead> <tr> <th>Jurisdiction</th> <th>Applicable State/US Territory</th> <th>Contractor</th> </tr> </thead> <tbody> <tr> <td>E (1)</td> <td>CA, HI, NV, AS, GU, CNMI</td> <td>Noridian Healthcare Solutions, LLC</td> </tr> <tr> <td>F (2 & 3)</td> <td>AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ</td> <td>Noridian Healthcare Solutions, LLC</td> </tr> <tr> <td>5</td> <td>KS, NE, IA, MO</td> <td>Wisconsin Physicians Service Insurance Corp (WPS)</td> </tr> <tr> <td>6</td> <td>MN, WI, IL</td> <td>National Government Services, Inc. (NGS)</td> </tr> <tr> <td>H (4 & 7)</td> <td>LA, AR, MS, TX, OK, CO, NM</td> <td>Novitas Solutions, Inc.</td> </tr> <tr> <td>8</td> <td>MI, IN</td> <td>Wisconsin Physicians Service Insurance Corp (WPS)</td> </tr> <tr> <td>N (9)</td> <td>FL, PR, VI</td> <td>First Coast Service Options, Inc.</td> </tr> <tr> <td>J (10)</td> <td>TN, GA, AL</td> <td>Cahaba Government Benefit Administrators, LLC</td> </tr> <tr> <td>M (11)</td> <td>NC, SC, WV, VA (excluding below)</td> <td>Palmetto GBA, LLC</td> </tr> <tr> <td>L (12)</td> <td>DE, MD, PA, NJ, DC (includes</td> <td>Novitas Solutions, Inc.</td> </tr> </tbody> </table>	Jurisdiction(s): N	NCD/LCD/Article Document (s): L34007 https://www.cms.gov/medicare-coverage-database/search/lcd-date-search.aspx?DocID=L34007&bc=gAAAAAAAAAAAAAA==	Jurisdiction(s): 5,8	NCD/LCD/Article Document (s): L34771 https://www.cms.gov/medicare-coverage-database/search/lcd-date-search.aspx?DocID=L34771&bc=gAAAAAAAAAAAAAA==	Jurisdiction	Applicable State/US Territory	Contractor	E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC	F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC	5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)	6	MN, WI, IL	National Government Services, Inc. (NGS)	H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.	8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)	N (9)	FL, PR, VI	First Coast Service Options, Inc.	J (10)	TN, GA, AL	Cahaba Government Benefit Administrators, LLC	M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC	L (12)	DE, MD, PA, NJ, DC (includes	Novitas Solutions, Inc.
Jurisdiction(s): N	NCD/LCD/Article Document (s): L34007 https://www.cms.gov/medicare-coverage-database/search/lcd-date-search.aspx?DocID=L34007&bc=gAAAAAAAAAAAAAA==																																					
Jurisdiction(s): 5,8	NCD/LCD/Article Document (s): L34771 https://www.cms.gov/medicare-coverage-database/search/lcd-date-search.aspx?DocID=L34771&bc=gAAAAAAAAAAAAAA==																																					
Jurisdiction	Applicable State/US Territory	Contractor																																				
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC																																				
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC																																				
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)																																				
6	MN, WI, IL	National Government Services, Inc. (NGS)																																				
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.																																				
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)																																				
N (9)	FL, PR, VI	First Coast Service Options, Inc.																																				
J (10)	TN, GA, AL	Cahaba Government Benefit Administrators, LLC																																				
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC																																				
L (12)	DE, MD, PA, NJ, DC (includes	Novitas Solutions, Inc.																																				

PHARMACY PRE-AUTHORIZATION CRITERIA



DRUG (S)	SCIG: Hizentra [®] , Gammagard Liquid [®] , Gamunex [®] -C, Gammaked [®] , Hyqvia, Cuvitru, Xembify (immune globulin SQ)		
		Arlington & Fairfax counties and the city of Alexandria in VA	
	K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
	15	KY, OH	CGS Administrators, LLC
P&T REVIEW HISTORY	11/2017, 5/18, 7/18		
REVISION RECORD	5/18, 1/20- added Xembify		