

Origination Date: 04/08	Revision Date(s): 04/09, 3/11
Developed By: Medical Criteria Committee	

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Approved: **Robert Neal Mills, MD** Date: 03/04/11

ODS Rx <sup>1.0</sup> <input type="checkbox"/>	ODS Rx <sup>2.0</sup> <input checked="" type="checkbox"/>	OEBB <input checked="" type="checkbox"/>	OHP <input type="checkbox"/>
NON-SPECIALTY <input type="checkbox"/>	SPECIALTY <input checked="" type="checkbox"/>		
PA <input checked="" type="checkbox"/>	QLL <input type="checkbox"/>	STEP THERAPY <input type="checkbox"/>	

**PA Description: Immunologic Agents/Immune Globulins**

**Products**

Carimune, Flebogamma, Gammagard, Gammaplex, Gamunex, Privigen, Hizentra, Vivaglobulin

**Description**

Immune globulins are collection of antibodies pooled from human serum. When administered, these agents boost your body's natural response to treat various immunodeficiency and blood disorders.

**FDA approved indications**

- Chronic inflammatory demyelinating polyneuropathy
- Idiopathic thrombocytopenic purpura
- Kawasaki syndrome
- Chronic B-Cell lymphocytic leukemia
- Primary immunodeficiency disease-Wiskott-Aldrich syndrome, congenital agammaglobulinemia, hypogammagobulinemia, immunodeficiency, severe combined immunodeficiencies,
- Immunoglobulin deficiency
- Bone marrow transplant
- Pediatric HIV infection

**Non-FDA approved indications**

- Guillian-Barre Syndrome
- Myasthenia Gravis
- Multiple Myeloma
- Multifocal motor neuropathy
- Postpoliomyelitis syndrome

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**Treatment Dose, Regimen, Duration**

Prior authorization is required for immune globulins to ensure safe and appropriate use. Approval is based on indications, dosages, frequency, site of administration, and duration of therapy that are FDA approved or supported by evidence-based literature.

**GUIDELINES FOR USE**

1. What is the patient's diagnosis?  
If the diagnosis is an FDA approved indication, continue to #2.  
If not, forward to clinical
2. What is the treatment dose?  
If treatment dose is within the approved dosing range, continue to #3.  
If not, forward to clinical
3. Is the patient under the supervision or care of specialist?  
If yes, continue to #4  
If no, forward to clinical
4. What clinical parameters will be monitored to establish treatment effectiveness?  
If submitted monitoring plan is consistent with effectiveness monitoring, continue to #5.  
If not, forward to clinical
5. **Approve for 3 months.**

References

1. **Flebogamma 5%** [package insert]. Los Angeles, CA: [Grifols USA, Inc](#); December 2003
2. **Gammagard Liquid** [package insert]. Westlake Village, CA: [Baxter Healthcare Corp](#); April 2005
3. **Flebogamma 10%** [package insert]. Los Angeles, CA: [Grifols USA Inc](#); November 2010
4. **Gamunex-C**[package insert]. Research Triangle Park, NC: [Talecris Biotherapeutics](#); 2010
5. **Vivaglobin** [package insert]. Marburg, Germany: [CSL Behring AG](#); January 2006
6. **Hizentra** [package insert]. Bern, Switzerland: [CSL Behring AG](#); March 2010
7. **Privigen** [package insert]. Bern, Switzerland: [CSL Behring AG](#); 2007
8. **GamaSTAN S/D** [package insert]. Research Triangle Park, NC: [Talecris Biotherapeutics, Inc](#); August 2007
9. <http://www.nlm.nih.gov/medlineplus/druginfo/meds/a682815.html>