

Intravenous Immune Globulin (IVIg) Use in Neurological and Neuromuscular Disorders

Type	Drug Guideline		
Category	Drug/Biologic		
Sub-Category	Nervous System		
Number	2005D0014B		
Approved By		Approval Date	
National Pharmacy & Therapeutics Committee		11/8/2005	(1.4.07)

Description	<p style="text-align: center;">After evaluating relevant benefit document language (exclusions or limitations), refer to Coverage sections of this document to determine coverage.</p> <p>This policy provides information about intravenous immune globulin and its recommended use in specific neurological and neuromuscular disorders.</p>
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Drug Products	<p>Gamimune N® Gammagard S/D® Gammar-P® Gamunex® Iveegam EN® Octagam® Panglobulin® Polygam S/D® Sandoglobulin® Venoglobulin-S® Venoglobulin-I®</p>
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Background


Intravenous immune globulin (IVIg) has been found to be an effective treatment for a number of primary immunodeficiency disorders and autoimmune diseases. Currently, there are no Us Food and Drug Administration (FDA) approved indications for the use of IVIg in neurological or neuromuscular disorders, but there is clinical evidence in the medical literature that IVIg is effective in Guillain-Barre syndrome, chronic inflammatory demyelinating polyneuropathy, relapsing-remitting multiple sclerosis, myasthenia gravis, multifocal motor neuropathy, stiff-man syndrome. IVIg has been studied in other autoimmune neurologic and neuromuscular disorders but the evidence

to support its use in these disorders is limited.

Audience

Targeted Population Enrollees, in all benefit plans, with neurological and neuromuscular conditions for which treatment with IVIg is proposed.

Coverage All reviewers must first identify member eligibility, any federal or state regulatory requirements and the plan benefit coverage prior to use of this policy.

Medicare Coverage  IVIg is covered for Medicare beneficiaries for treatment of:

- Guillain-Barre syndrome,
- Chronic inflammatory demyelinating polyneuropathy,
- Relapsing-remitting multiple sclerosis,
- Myasthenia gravis, and
- Multifocal motor neuropathy.

Note: Compliance with Local Medical Review Policy (LMRP) is required where applicable.

Coverage Rationale

Intravenous immune globulin is proven in the treatment of Guillain-Barre Syndrome, chronic inflammatory demyelinating polyneuropathy, relapsing-remitting multiple sclerosis, myasthenia gravis, multifocal motor neuropathy, and stiff-man syndrome.

Intravenous immune globulin is unproven for neurological and neuromuscular diagnoses other than those listed above because of inadequate clinical evidence of safety and/or efficacy in published peer-reviewed medical literature. Please refer to a list of specific diagnoses and conditions under Clinical Recommendations.

Clinical Information

Clinical Recommendations

Note: This section provides detailed information about the clinical intended use for the treatment that is the topic of this Technology Assessment. The detailed information provided in this section is NOT used to decide whether or not a service is paid for. Rather, it provides background information and rationale about the scientifically appropriate use of the treatment, for discussion purposes with providers. See "Coverage" section to determine what procedure(s) are covered/non-covered (i.e., paid for where such benefits are available).