ATRIO HEALTH PLANS

Panzyga

Panzyga (immune globulin-ifas) J1576

Prior Authorization Request

Medicare Part B Form

*Instructions: * Indicates required information – Form may be returned if required information is not provided. Please fax this request to the appropriate fax number listed at the bottom of the page.*

☐	**Standard Request– (72 Hours)**	☐	**Urgent Request** (standard time frame could place the member's life, health or ability in serious jeopardy)
	Date Requested _____		
	Requestor _____ Clinic name: _____ Phone / Fax		

MEMBER INFORMATION

*Name:_____ *ID#:_____ *DOB:_____

PRESCRIBER INFORMATION

*Name:_____ ☐MD ☐FNP ☐DO ☐NP ☐PA *Phone:_____

*Address:_____ *Fax:_____

DISPENSING PROVIDER / ADMINISTRATION INFORMATION

*Name:_____ Phone:_____

*Address:_____ Fax:_____

PROCEDURE / PRODUCT INFORMATION

HCPC Code	Name of Drug	Dose (Wt: _____ kg Ht:_____)	Frequency	End Date if known

☐ **Self-administered** ☐ **Provider-administered** ☐ **Home Infusion**

☐Chart notes attached. **Other important information:**_____

Diagnosis: ICD10: _____ **Description**: _____

☐ Provider attests the diagnosis provided is an FDA-Approved indication for this drug

CLINICAL INFORMATION

☐ New Start or Initial Request: (Clinical documentation required for all requests)

☐ **Primary Humoral Immunodeficiency**
- ☐ Patient has diagnosed primary immunodeficiency disease (e.g., CVID, XLA, IgG subclass deficiency with specific antibody deficiency) AND
- ☐ Documented history of recurrent serious bacterial infections AND
- ☐ Baseline IgG level <500 mg/dL or subnormal levels with documented specific antibody deficiency AND
- ☐ Failure of prophylactic antibiotics or contraindication to antibiotic use

☐ **Idiopathic Thrombocytopenic Purpura (ITP)**
- ☐ Patient has confirmed diagnosis of ITP with platelet count <30,000/µL AND
- ☐ Patient has active bleeding or high risk of bleeding OR
- ☐ Patient requires platelet count increase prior to surgery AND
- ☐ Patient has failed, intolerant, or has contraindication to corticosteroids

☐ **Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)**
- ☐ Patient has confirmed diagnosis of CIDP per clinical and electrodiagnostic criteria AND
- ☐ Patient has moderate to severe disability AND
- ☐ Prescribed by or in consultation with neurologist

☐ **Multifocal Motor Neuropathy (MMN)**
- ☐ Patient has confirmed diagnosis of MMN per clinical and electrodiagnostic criteria AND
- ☐ Prescribed by or in consultation with neurologist

☐ **Myasthenia Gravis**
- ☐ Patient has confirmed diagnosis of moderate to severe myasthenia gravis AND
- ☐ Patient has acute exacerbation or is preparing for surgery OR
- ☐ Patient has failed, intolerant, or has contraindication to immunosuppressive therapies AND
- ☐ Prescribed by or in consultation with neurologist

☐ **Kawasaki Disease**
- ☐ Patient is pediatric (or adult with incomplete Kawasaki) AND
- ☐ Meets diagnostic criteria for Kawasaki disease AND
- ☐ Treatment initiated within 10 days of fever onset

☐ **Secondary Immunodeficiency with Specific Antibody Deficiency**
- ☐ Patient has secondary immunodeficiency (e.g., CLL, multiple myeloma, post-hematopoietic stem cell transplant) AND
- ☐ Documented history of serious or recurrent infections AND
- ☐ Documented specific antibody deficiency (e.g., poor response to vaccines)

If not, please provide **clinical rationale** for formulary exception: _____
_____

☐ Continuation Requests: (Clinical documentation required for all requests)
- ☐ Patient had an **adequate response** or **significant improvement** while on this medication.
  - ☐ Medical record documentation of positive response is included

If not, please provide clinical rationale for continuing this medication: _____
_____

ACKNOWLEDGEMENT

Request By (Signature Required): _____Date:_____/____/____

Any person who knowingly files a request for authorization of coverage of a medical procedure or service with the intent to injure, defraud or deceive any insurance company by providing materially false information or conceals material information for the purpose of misleading, commits a fraudulent insurance act, which is a crime and subjects such person to criminal and civil penalties. **THIS AUTHORIZATION IS NOT A GUARANTEE OF PAYMENT.** PAYMENT IS BASED ON BENEFITS IN EFFECT AT THE TIME OF SERVICE, MEMBER ELIGIBILITY AND MEDICAL NECESSITY.

Prior Authorization Group – Panzyga Prior Authorization

Drug Name(s):

PANZYGA **IMMUNE GLOBULIN-IFAS**

Criteria for approval of Non-Formulary/Preferred Drug:

1. Prescribed for an approved FDA diagnosis (as listed below):
2. Member does not have any clinically relevant contraindications, or CMS/Plan exclusions, to the requested drug.

- If the member meets all these criteria, they may be approved by the Plan for the requested drug.
- Quantity limits and Tiering will be determined by the Plan, in accordance with the Label.
- Continuation Requests: Provider must verify continued clinical benefit in confirmatory trial(s).

Exclusion Criteria:

N/A

Prescriber Restrictions:

N/A

Coverage Duration:

Approval will be for 6 months

FDA Indications:

Panzyga

- Immune thrombocytopenia (Chronic)View additional information.
- Inflammatory demyelinating polyradiculoneuropathy, chronicView additional information.
- Measles; Prophylaxis - Primary immune deficiency disorderView additional information.
- Primary immune deficiency disorder

Off-Label Uses:

N/A

Age Restrictions:

Indicated for patients 2 years or older.

Other Clinical Consideration:

Intravenous (Solution)

- **Warning: Thrombosis, Renal Dysfunction, and Acute Renal Failure**
- **Thrombosis may occur with immune globulin intravenous (IGIV) products, including immune globulin-ifas. Risk factors may include: advanced age, prolonged immobilization, hypercoagulable conditions, history of venous or arterial thrombosis, use of estrogens, indwelling vascular catheters, hyperviscosity, and cardiovascular risk factors.**
- **Renal dysfunction, acute renal failure, osmotic nephropathy, and death may occur with the administration of IGIV products in predisposed patients. Renal dysfunction and acute renal failure occur more commonly in patients receiving IGIV products containing sucrose. Immune globulin-ifas does not contain sucrose.**
- **For patients at risk of thrombosis, renal dysfunction, or renal failure, administer immune globulin-ifas at the minimum infusion rate practicable. Ensure adequate hydration in patients before administration. Monitor for signs and symptoms of thrombosis and assess blood viscosity in patients at risk for hyperviscosit**

Resources:

https://www.micromedexsolutions.com/micromedex2/librarian/CS/00A0C1/ND_PR/evidencexpert/ND_P/evidencexpert/DUPLICATIONSHIELDSYNC/475F0D/ND_PG/evidencexpert/ND_B/evidencexpert/ND_AppProduct/evidencexpert/ND_T/evidencexpert/PFActionId/evidencexpert.GoToDashboard?docId=932558&contentSetId=100&title=Immune+Globulin-ifas&servicesTitle=Immune+Globulin-ifas&brandName=Panzyga&UserMdxSearchTerm=panzyga#