

ASCENIV™
IMMUNE GLOBULIN INTRAVENOUS
(HUMAN) — slra 10% LIQUID

**DESIGNED TO
DELIVER™**

ASCENIV GUIDE TO BILLING AND REIMBURSEMENT

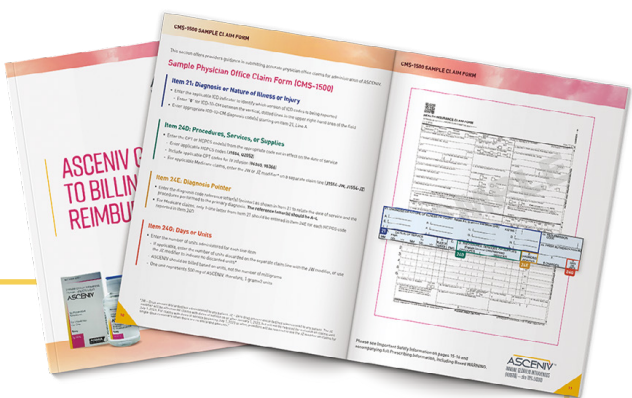


Please see Important Safety Information on
pages 15-16 and full Prescribing Information at
www.asceniv.com, including Boxed WARNING,
for ASCENIV.

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Please see Important Safety Information on pages 15-16 and full Prescribing Information at www.asceniv.com, including Boxed WARNING.



Introduction

ADMA Biologics has developed this Guide to Billing and Reimbursement to help assist healthcare providers in understanding third-party payment for ASCENIV, and to **provide you with general coding information and claims submission details for ASCENIV**. ADMA is committed to providing billing and coding information for the following FDA-approved indication:

ASCENIV (immune globulin intravenous, human-sIra) is a 10% immune globulin liquid for intravenous injection, indicated for the treatment of primary humoral immunodeficiency (PI) in adults and pediatric patients (2 years of age and older).

This section describes the types of codes that are likely to be most relevant to claims for ASCENIV. ASCENIV is a solution for infusion to be administered intravenously (IV) in an infusion center, physician’s office, or at home by a trained healthcare provider.

International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10–CM) Diagnosis Codes¹

ICD-10–CM diagnosis codes are used for identifying and documenting a patient’s specific diagnosis. These codes are used by all healthcare providers and are recognized by all insurers. Local coverage determinations and articles should be consulted for additional covered indications.

D69	Purpura and other hemorrhagic conditions
D69.3	Immune thrombocytopenia purpura Hemorrhagic (thrombocytopenic) purpura Idiopathic thrombocytopenic purpura Tidal platelet dysgenesis
D80	Immunodeficiency with predominantly antibody defects
D80.0*	Hereditary hypogammaglobulinemia Autosomal recessive agammaglobulinemia (Swiss type) X-linked agammaglobulinemia [Bruton] (with growth hormone deficiency)
D80.1	Nonfamilial hypogammaglobulinemia Agammaglobulinemia with immunoglobulin-bearing B-lymphocytes Common variable agammaglobulinemia [CVAgamma] Hypogammaglobulinemia NOS
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]
D80.6*	Antibody deficiency with near-normal immunoglobulins or with hyperimmunoglobulinemia
D80.7*	Transient hypogammaglobulinemia of infancy
D80.8	Other immunodeficiencies with predominantly antibody defects Kappa light chain deficiency
D80.9	Immunodeficiency with predominantly antibody defects, unspecified

Table continues on the next page.

¹Please Note: Medicare Part B–approved diagnosis codes for treatment with ASCENIV in the home. All other diagnoses may qualify for coverage under Medicare Part D plans.²

Please see Important Safety Information on pages 15–16 and full Prescribing Information at www.asceniv.com, including Boxed WARNING.



ICD-10-CM Diagnosis Codes¹ (continued)

D81	Combined immunodeficiencies
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
D81.4	Nezelof's syndrome
D81.5*	Purine nucleoside phosphorylase [PNP] deficiency
D81.6*	Major histocompatibility complex class I deficiency <i>Bare lymphocyte syndrome</i>
D81.7*	Major histocompatibility complex class II deficiency
D81.82*	Activated Phosphoinositide 3-kinase Delta Syndrome [APDS]
D81.89*	Other combined immunodeficiencies
D81.9*	Combined immunodeficiencies, unspecified <i>Severe combined immunodeficiency disorder [SCID] NOS</i>
D82	Immunodeficiency associated with major other defects
D82.0*	Wiskott-Aldrich syndrome <i>Immunodeficiency with thrombocytopenia and eczema</i>
D82.1*	Di George's syndrome <i>Pharyngeal pouch syndrome</i> <i>Thymic aplasia</i> <i>Thymic aplasia or hypoplasia with immunodeficiency</i>
D82.2	Immunodeficiency with short-limbed stature
D82.3	Immunodeficiency following hereditary defective response to Epstein-Barr virus <i>X-linked lymphoproliferative disease</i>
D82.4*	Hyperimmunoglobulin E [IgE] syndrome
D82.8	Immunodeficiency associated with other specified major defects
D82.9	Immunodeficiency associated with major defect, unspecified

Table continues on the next page.

¹Please Note: Medicare Part B-approved diagnosis codes for treatment with ASCENIV in the home. All other diagnoses may qualify for coverage under Medicare Part D plans.²

ICD-10-CM Diagnosis Codes¹ (continued)

D83	Common variable immunodeficiency
D83.0*	Common variable immunodeficiency with predominant abnormalities of B-cell numbers and function
D83.1*	Common variable immunodeficiency with predominant immunoregulatory T-cell disorders
D83.2*	Common variable immunodeficiency with autoantibodies to B- or T-cells
D83.8*	Other common variable immunodeficiencies
D83.9*	Common variable immunodeficiency, unspecified
D84	Other immunodeficiencies
D84.9	<i>Immunodeficiency, unspecified</i> <i>Immunocompromised NOS</i> <i>Immunodeficient NOS</i> <i>Immunosuppressed NOS</i>
G11	Hereditary ataxia
G11.3*	Cerebellar ataxia with defective DNA repair <i>Ataxia telangiectasia [Louis-Bar]</i>
G61	Inflammatory polyneuropathy
G61.81	Chronic inflammatory demyelinating polyneuritis

²Please Note: Medicare Part B-approved diagnosis codes for treatment with ASCENIV in the home. All other diagnoses may qualify for coverage under Medicare Part D plans.²

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Healthcare Common Procedure Coding System (HCPCS) Code³

HCPCS codes are used for billing drugs and services to Medicare, Medicaid, and Commercial payers. The HCPCS description for ASCENIV specifies that each billing unit is the equivalent of 500 mg. Therefore, each gram of ASCENIV represents 2 billable units. **For example**, if 30 grams of ASCENIV are administered, 60 units should be billed on the claim form.

The HCPCS J1554 code for ASCENIV is listed by CMS and Medicare Part B Administration Contractors in their National Drug Code (NDC) files.

Code	Description
J1554	Injection, immune globulin (ASCENIV), 500 mg
Additional information required by most payers on claim forms:	- Branded/generic name - Strength - Dosage administered - Route of administration - National Drug Code (NDC)
Some payers may also request:	- Package insert/Prescribing information - Drug purchase invoice - Documentation to support medical necessity (eg, Letter/Statement of Medical Necessity)

ASCENIV National Drug Codes (NDCs)

An NDC is a universal, unique, 3-segment number identifying drugs by manufacturer, dosage, and package size. NDCs are used for billing drugs and biologicals.

Billing NDC	Inner package NDC	Concentration
69800-0250-01	69800-0250-02	5 g/50 mL

Current Procedural Terminology (CPT®)* Codes⁴

CPT codes describe the medical, surgical, diagnostic, and therapeutic services and procedures.

Code	Description
96365	IV infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); initial, up to 1 hour
96366	IV infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); each additional hour (list separately in addition to code for primary procedure)

*CPT is a registered trademark of the American Medical Association (AMA). All rights reserved.

Codes for Home Specialty Pharmacies and Home Infusion Providers

Home Infusion Therapy³

HCPCS per diem S-codes are used by commercial payers and Medicaid to report drugs, services, and supplies. These codes are not payable by Medicare.

Code	Description
S9338	Home infusion therapy, immunotherapy, administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem

Permanent IVIG In-Home Coverage—Effective January 1, 2024^{3,5}

Congress enacted the Consolidated Appropriations Act of 2023, which made the previous IVIG Demonstration for IVIG in-home coverage now a permanent benefit, with no need for patients or eligible suppliers to enroll in the Demonstration. Effective January 1, 2024, the Act provides for a permanent, bundled payment for items and services related to administration of IVIG in the home of a patient with a diagnosis of Primary Immune Deficiency Disease (PIDD). Payment covers cost of nursing services and supplies, including an infusion set and tubing, for the provision of IVIG administration in the home by a durable medical equipment supplier, per visit.

To qualify, providers must complete the claims procedurally and indicate both the drug J code for ASCENIV [“J1554 (Injection, immune globulin (ASCENIV), 500 mg)”] and the bundle code Q2052 (“Q2052 - Services, supplies, and accessories used in the home under Medicare Intravenous immune globulin (IVIG) demonstration”). Q2052 does not have to be included on same claim as the allowable J code. Providers should report visit length in 15-minute increments (15 minutes=1 unit) when billing for IVIG (Q2052). Claims may be denied if one of the allowable drug J codes is not on the same claim.

Code	Description
Q2052	Services, supplies and accessories used in the home under the Medicare IVIG demonstration

Codes are subject to change.

Please see Important Safety Information on pages 15-16 and full Prescribing Information at www.asceniv.com, including Boxed WARNING.



This section offers providers guidance in submitting accurate physician office claims for administration of ASCENIV.

Sample Physician Office Claim Form (CMS-1500)

Item 21: Diagnosis or Nature of Illness or Injury

- Enter the applicable ICD indicator to identify which version of ICD codes is being reported
 - Enter "0" for ICD-10-CM between the vertical, dotted lines in the upper right-hand area of the field
- Enter appropriate ICD-10-CM diagnosis code(s) starting on Item 21, Line A

Item 24D: Procedures, Services, or Supplies

- Enter the CPT or HCPCS code(s) from the appropriate code set in effect on the date of service
 - Enter applicable HCPCS codes (**J1554, Q2052**)
 - Include applicable CPT codes for IV infusion (**96365, 96366**)
 - For applicable Medicare claims, enter the JW or JZ modifier* on a separate claim line (**J1554-JW, J1554-JZ**)

Item 24E: Diagnosis Pointer

- Enter the diagnosis code reference letter(s) (pointer) as shown in Item 21 to relate the date of service and the procedures performed to the primary diagnosis. **The reference letter(s) should be A–L**
- For Medicare claims, only 1-line letter from Item 21 should be entered in Item 24E for each HCPCS code reported in Item 24D

Item 24G: Days or Units

- Enter the number of units administered for each line item
 - If applicable, enter the number of units discarded on the separate claim line with the JW modifier, or use the JZ modifier to indicate no discarded units*
 - ASCENIV should be billed based on units, not the number of milligrams
 - One unit represents 500 mg of ASCENIV, therefore, 1 gram=2 units

*JW – Drug amount discarded/not administered to any patient. JZ – Zero drug amount discarded/not administered to any patient. The JZ modifier will be effective for claims with dates of service on or after January 1, 2023, but will not be required for inclusion on claims until July 1, 2023. For claims with dates of service beginning July 1, 2023 or after, providers will be required to use the JZ modifier on claims for single-dose containers when there are no discarded amounts.⁶

HEALTH INSURANCE CLAIM FORM

APPROVED BY NATIONAL UNIFORM CLAIM COMMITTEE (NUCC) 02/12

PICA		PICA	
1. MEDICARE ☐ MEDICAID ☐ TRICARE ☐ CHAMPVA ☐ GROUP HEALTH PLAN ☐ FECA BLK LUNG ☐ OTHER ☐	1a. INSURED'S I.D. NUMBER (For Program in Item 1)		
2. PATIENT'S NAME (Last Name, First Name, Middle Initial)	3. PATIENT'S BIRTH DATE MM DD YY	SEX M ☐ F ☐	4. INSURED'S NAME (Last Name, First Name, Middle Initial)
5. PATIENT'S ADDRESS (No., Street)	6. PATIENT RELATIONSHIP TO INSURED Self ☐ Spouse ☐ Child ☐ Other ☐		7. INSURED'S ADDRESS (No., Street)
CITY	STATE	CITY	STATE
ZIP CODE	TELEPHONE (Include Area Code)	ZIP CODE	TELEPHONE (Include Area Code)
9. OTHER INSURED'S NAME (Last Name, First Name, Middle Initial)		11. INSURED'S POLICY GROUP OR FECA NUMBER	
a. OTHER INSURED'S POLICY OR GROUP NUMBER	a. EMPLOYMENT? (Current or Previous) YES ☐ NO ☐	a. INSURED'S DATE OF BIRTH MM DD YY	
b. RESERVED FOR NUCC USE	b. AUTO ACCIDENT? YES ☐ NO ☐ PLACE (State)	b. OTHER CLAIM ID (Designated by NUCC)	
c. RESERVED FOR NUCC USE	c. OTHER ACCIDENT? YES ☐ NO ☐	c. INSURANCE PLAN NAME OR PROGRAM NAME	
d. INSURANCE PLAN NAME OR PROGRAM NAME	10d. CLAIM CODES (Designated by NUCC)	d. IS THERE ANOTHER HEALTH BENEFIT PLAN? YES ☐ NO ☐ If yes, complete items 9, 9a, and 9d.	
12. PATIENT'S OR AUTHORIZED PERSON'S SIGNATURE I authorize the release of any medical or other information necessary to process this claim. I also request payment of government benefits either to myself or to the party who accepts assignment below. SIGNED _____ DATE _____			
14. DATE OF CURRENT ILLNESS, INJURY, or PREGNANCY (LMP) MM DD YY QUAL. _____		16. DATES PATIENT UNABLE TO WORK IN CURRENT OCCUPATION FROM MM DD YY TO MM DD YY	
17. NAME OF REFERRING PROVIDER OR OTHER SOURCE 17a. _____ 17b. NPI _____		18. HOSPITALIZATION DATES RELATED TO CURRENT SERVICES FROM MM DD YY TO MM DD YY	
19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC)		20. OUTSIDE LAB? YES ☐ NO ☐ \$ CHARGES _____	

21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY Relate A-L to service line below (24E)										ICD Ind.		22. RESUBMISSION CODE		ORIGINAL REF. NO.							
A. _____ B. _____ C. _____ D. _____																					
E. _____ F. _____ G. _____ H. _____																					
I. _____ J. _____ K. _____ L. _____																					
21 A. DATE(S) OF SERVICE				B. PLACE OF SERVICE		C. EMG		D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances)				E. DIAGNOSIS POINTER		F. \$ CHARGES		G. DAYS OR UNITS		H. EPSDT Family Plan		I. ID. QUAL.	
MM	DD	YY	MM	DD	YY			CPT/HCPCS	MODIFIER												

21 A. DATE(S) OF SERVICE										B. PLACE OF SERVICE		C. EMG		D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances)				E. DIAGNOSIS POINTER		F. \$ CHARGES		G. DAYS OR UNITS		H. EPSDT Family Plan		I. ID. QUAL.	
MM	DD	YY	MM	DD	YY			CPT/HCPCS	MODIFIER																		
3														24D				24E		24G							
4																											
5																											
6																											
25. FEDERAL TAX I.D. NUMBER						SSN EIN		26. PATIENT'S ACCOUNT NO.				27. ACCEPT ASSIGNMENT? For print, circle one below		28. TOTAL CHARGE \$		29. AMOUNT PAID \$		30. Rsvd for NUCC Use									
31. SIGNATURE OF PHYSICIAN OR SUPPLIER INCLUDING DEGREES OR CREDENTIALS (I certify that the statements on the reverse apply to this bill and are made a part thereof.)						32. SERVICE FACILITY LOCATION INFORMATION						33. BILLING PROVIDER INFO & PH # ()															
SIGNED _____						a. _____						b. _____															

NUCC Instruction Manual available at: www.nucc.org

PLEASE PRINT OR TYPE

APPROVED OMB-0938-1197 FORM 1500 (02-12)

Please see Important Safety Information on pages 15-16 and full Prescribing Information at www.asceniv.com, including Boxed WARNING.

ASCENIV
IMMUNE GLOBULIN INTRAVENOUS
(HUMAN) — sra 10% LIQUID

Submitting claims when the billed amount exceeds \$99,999.99

One general rule pertaining to an 837P (Part B (DME) electronic claim) transaction is the maximum number of characters submitted in any dollar amount field is **seven characters**. Claims containing a dollar amount more than \$99,999.99 will be rejected.⁷

The Health Care Claim: Professional (837P)* can be found on the CEDI - Technical Specifications website and contains information regarding the X12 837 Professional claim format including Medicare specific information and requirements. This is intended to be used in addition to the other X12 837P reference documents. This document clarifies and specifies data content when exchanging transactions electronically with Medicare.

PLEASE NOTE: The information contained in this guide is provided for informational purposes only. Every Medicare Administrative Contractor (MAC) is different and outlines how they require claims to be processed. Providers are encouraged to contact their local (MAC) for additional information on how to properly file claims that are over the \$99,999.99.

Example

Claims for services that exceed this amount will have to be submitted on separate claims as follows:

Claim 1

- Submit the service with an acceptable dollar amount (< 9999999.) See example below, splitting total.
(Do not use dollar signs, decimals, dashes, commas for dollar amounts.)
- In the narrative field, identify this as, "Claim 1 of 2; Dollar amount exceeds charge line amount."

Claim 2

- Enter the charge as the remaining dollar amount from the total split.
- In the narrative field, identify this as, "Claim 2 of 2; Remaining dollar amount from Claim 1 amount exceeds charge line amount."

You must note in the narrative the reason why the claim is split this way. It will deny as a duplicate without the narrative.

Narrative must be added in loop 2400 (line note), segment NTE02 (NTE01=ADD) of the ANSI X12N, version 5010A1 professional electronic claim format or on Item 19 of the paper claim form in the narrative field

Also, when splitting the charge of the service, be sure the **dollar amounts are slightly different**, as this will prevent the system from assuming the two claims are an exact duplicate.

- **Example:** If the charge for a service is \$100,000.00, submit the charge on Claim 1 as 5200000; on Claim 2 submit the charge as 4800000. Ensure narrative is added to line 19. (Do not use dollar signs, decimals, dashes, commas for dollar amounts.)

Simplify access to ASCENIV for your patients

When you have decided ASCENIV is appropriate for your patient, ADvantage Ig may help your patients with understanding their coverage and potential for financial support



Hub Services Assistance:

- Answer general ADvantage Ig support services questions and provide healthcare providers with educational material
- Educate your patients about their insurance benefits
- Help patients navigate their assistance options so they can pay the lowest amount possible
- Provide patients or providers with assistance in locating alternative funding and other payment options such as nonprofit patient assistance foundation support
- Assist buy/bill and specialty pharmacies with insurance benefits verification, determination of patient coverage, cost-share responsibility, prior authorization (PA), and predetermination requirements
- Verify code coverage and claims support



Field Reimbursement Manager Support:

- Share local and regional payer access overview specific to your office and geography
- Provider-specific payer analysis for payer policy and disease state criteria
- Education and onsite support for best practices for prior approval, appeals (including Letter of Medical Necessity guidance), and claims submissions best practice
- Coach provider support team on ADvantage Ig cost share program, enrollment best practices, and specific billing coding needs



Next Steps:

- Connect with your Hub Services or Field Reimbursement Manager
- Complete ADvantage Ig enrollment form via DocuSign or fax enrollment form to 1-833-216-0441

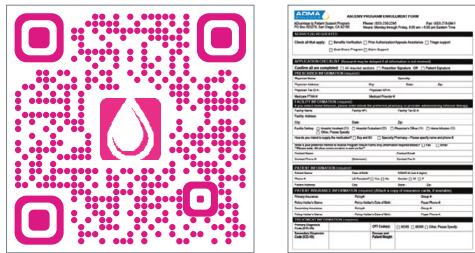
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*Centers for Medicare & Medicaid Services (CMS) Standard Companion Guide Health Care Claim Professional (837P).

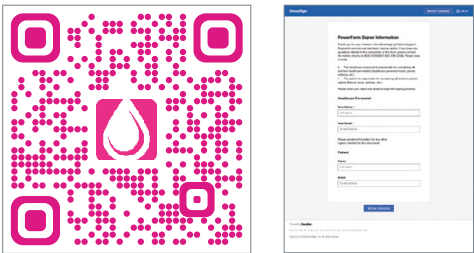
Enroll your patients in ADMA ADvantage Ig™ for support

Scan QR code below for PDF Option



PDF Option

Scan QR code below for DocuSign Option



DocuSign Option



For Benefits Verification and guidance on Prior Authorization, Medical Exception, and Appeals, please contact us:
1-833-ADMA-BIO (1-833-236-2246) • Monday-Friday • 9 AM to 6 PM ET
Requests received by 2 PM ET are typically completed the same day.

Summary of eligibility requirements

- Patient must be a US resident
- Must have private commercial insurance
- IVIG treatment must be covered by insurance
- The ADvantage Ig Patient Support Program provides deductible, copay or coinsurance and administration support only for IVIG products from ADMA Biologics
- Program covers up to a fixed amount of out-of-pocket costs per calendar year for eligible patients, after the patient has paid the first \$75 of their required deductible, copay or coinsurance and administration amount. The program will pay the amount covered by the payer’s allowed amount as indicated on the explanation of benefits (EOB)
- The Program does not cover office/facility copays not directly associated with IGIV treatment or any other costs excluded by the Program guidelines not specifically mentioned here, which are subject to change

Terms and Conditions

This offer is valid only in the United States. Patient must be prescribed an IVIG product manufactured by ADMA Biologics, Inc. and prescribed by a licensed practitioner. Eligible patients must have private commercial insurance that covers medication costs for these products, and acceptance of this offer must be consistent with the terms of that insurer’s drug benefit. Patients who pay cash or who are enrolled in or participate in any type of government insurance or reimbursement programs, including but not limited to Medicare, Medicare Advantage, Medicare Part D, Medicaid, Medigap, TRICARE, Veterans Affairs (VA), the Department of Defense (DoD) or other federally funded or state funded healthcare programs, are not eligible. Patients who move from commercial to federally funded or state-funded insurance will no longer be eligible for the program. Proof required for receiving payment for out-of-pocket drug costs must be a valid Explanation of Benefits (EOB) or specialty pharmacy invoice, which must be submitted within 120 days of processed claim. As a condition precedent of the cost share support provided under this program, e.g., copay or coinsurance amounts paid to administering providers, participating patients and administering providers are obligated to inform insurance companies and third-party payers of any benefits they receive and the value of this program, as required by contract or otherwise. Patient/Guardian may not seek reimbursement for value received from the Cost Share Program from any third-party payers, including flexible spending accounts or healthcare savings accounts.

Void where prohibited by law, taxed, or restricted. Additional terms and conditions may apply. ADMA Biologics, Inc. may determine eligibility, monitor participation, and modify or discontinue any aspect of this program at any time.

Indication

ASCENIV™ (immune globulin intravenous, human–slra) is a 10% immune globulin liquid for intravenous injection, indicated for the treatment of primary humoral immunodeficiency (PI) in adults and pediatric patients (2 years of age and older). PI includes, but is not limited to, the humoral immune defect in congenital agammaglobulinemia, common variable immunodeficiency (CVID), X linked agammaglobulinemia, Wiskott–Aldrich syndrome, and severe combined immunodeficiencies (SCID).

Important Safety Information for ASCENIV

- WARNING: THROMBOSIS, RENAL DYSFUNCTION AND ACUTE RENAL FAILURE**
- Thrombosis may occur with immune globulin intravenous (IGIV) products, including ASCENIV. 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 nephrosis, and death may occur with the administration of IGIV products in predisposed patients. Such events require immediate medical intervention, if not recognized or managed appropriately, may result in persistent or significant disability or lead to fatal outcome.
 - For patients at risk of thrombosis, renal dysfunction or renal failure, administer ASCENIV at the minimum dose and 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 hyperviscosity.

Contraindications

- ASCENIV is contraindicated in:
- Patients who have had an anaphylactic or severe systemic reaction to the administration of human immune globulin.
 - IgA-deficient patients with antibodies to IgA and a history of hypersensitivity.

Warnings and Precautions

Severe hypersensitivity reactions may occur with IGIV products, including ASCENIV. In case of hypersensitivity, discontinue ASCENIV infusion immediately and institute appropriate treatment. Medications such as epinephrine should be available for treatment of acute hypersensitivity reactions. Patients with known antibodies to IgA may have a greater risk of developing severe hypersensitivity and anaphylactic reactions.

Thrombosis may occur following treatment with immune globulin products, including ASCENIV, and in the absence of known risk factors. Consider baseline assessment of blood viscosity in patients at risk for hyperviscosity and ensure adequate hydration before administration. For patients at risk of thrombosis, administer ASCENIV at the minimum dose and infusion rate practicable. Monitor for signs and symptoms of thrombosis and assess blood viscosity in patients at risk for hyperviscosity.

Acute renal dysfunction, acute renal failure, acute tubular necrosis, proximal tubular nephropathy, osmotic nephrosis, and death may occur upon use of human IGIV products. Ensure that patients are not volume depleted before administering ASCENIV. Periodic monitoring of renal function and urine output is particularly important in patients at increased risk of developing acute renal failure. Assess renal function, including measurement of blood urea nitrogen (BUN) and serum creatinine, before the initial infusion of ASCENIV and at appropriate intervals thereafter. Discontinue ASCENIV if renal function deteriorates. In at risk patients, administer ASCENIV at the minimum infusion rate practicable.

Hyperproteinemia, hyperviscosity, and hyponatremia may occur in patients receiving IGIV treatment, including ASCENIV. It is critical to clinically distinguish true hyponatremia from a pseudohyponatremia that is associated with or causally related to hyperproteinemia. Treatment aimed at decreasing serum free water in patients with pseudohyponatremia may lead to volume depletion, a further increase in serum viscosity, and a possible predisposition to thrombotic events.

Please see additional Important Safety Information on back cover and full Prescribing Information at www.asceniv.com, including Boxed WARNING.

Important Safety Information for ASCENIV (cont'd)

Warnings and Precautions (cont'd)

Aseptic meningitis syndrome (AMS) may occur with IGIV treatments, including ASCENIV. AMS usually begins within several hours to 2 days following IGIV treatment. The risk of AMS may be higher with high doses (≥ 2 g/kg) and/or rapid infusion of IGIV. Conduct a thorough neurological examination on patients exhibiting signs and symptoms of AMS, including cerebrospinal fluid (CSF) studies, to rule out other causes of meningitis. Discontinuation of IGIV treatment has resulted in remission of AMS within several days without sequelae.

Hemolysis may occur after administration of IGIV products, including ASCENIV, due to the presence of blood group antibodies that can act as hemolysins and induce in vivo coating of red blood cells (RBCs) with immunoglobulin, causing a positive direct antiglobulin test and hemolysis. The risk factors for hemolysis include high doses (e.g., ≥ 2 g/kg) given either as a single administration or divided over several days, non-O blood group, and an underlying inflammatory disease condition. Monitor patients for clinical signs and symptoms of hemolysis, including appropriate confirmatory laboratory testing.

Transfusion-Related Acute Lung Injury (TRALI) may occur in patients following IGIV treatment, including ASCENIV. Monitor patients for pulmonary adverse reactions. If TRALI is suspected immediately stop ASCENIV infusion and perform appropriate tests for presence of anti-neutrophil antibodies and anti-human leukocyte (HLA) antibodies in both product and patient's serum. Manage patients using oxygen therapy with adequate ventilatory support as appropriate.

There is risk of transmitting infectious agents including viruses, the variant Creutzfeldt-Jakob disease (vCJD) and the Creutzfeldt-Jakob disease (CJD) agent with ASCENIV administration because it is manufactured using human blood. All infections suspected to have been transmitted by ASCENIV should be reported by the physician or other healthcare provider to ADMA Biologics at (1-800-458-4244).

After infusion of immunoglobulin, the transitory rise of the various passively transferred antibodies in the patient's blood may yield positive serological testing results, with the potential for misleading interpretation. Passive transmission of antibodies to erythrocyte antigens (e.g., A, B, and D) may cause a positive direct or indirect antiglobulin (Coombs') test.

Adverse Reactions

The most common adverse reactions to ASCENIV ($\geq 5\%$ of study patients) were headache, nausea, otitis, sinusitis, fatigue, chest pain, muscle spasm, acute sinusitis, diarrhea, hypersensitivity, viral rash, vomiting, bronchitis, epistaxis, muscle pain, oropharyngeal pain, pain in extremity and itching.

To report SUSPECTED ADVERSE REACTIONS, contact ADMA Biologics at (1-800-458-4244) or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch. For additional safety information about ASCENIV, please see full Prescribing Information.

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Please see Important Safety Information on pages 15-16 and full Prescribing Information at www.asceniv.com, including Boxed WARNING.

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