2006 Provider Coding/Billing Information

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NovoSeven®
Coagulation Factor VIIa
(Recombinant)

Contents

About NovoSeven® Coagulation Factor VIIa (Recombinant)

NovoSeven is indicated for the treatment of bleeding episodes in hemophilia A or B patients with inhibitors to FVIII or FIX; prevention of bleeding in surgical interventions or invasive procedures in hemophilia A or B patients with inhibitors to FVIII or FIX; treatment of bleeding episodes in patients with congenital FVII deficiency; prevention of bleeding in surgical interventions or invasive procedures in patients with congenital FVII deficiency.

Comforting providers is just as important as comforting patients.

At Novo Nordisk, we strive to do all we can to bring ease to the hectic lives of care providers. That's why we aim to provide you and your patients with the resources you need for insurance and reimbursement management.

This booklet will help you manage the issues surrounding insurance reimbursement for NovoSeven, including:

- Coding, billing, and reimbursement procedures (including sample claim forms)
- Responding to denial of coverage

1-877-NOVO-777 (1-877-668-6777)

Monday through Friday 9 AM to 8 PM ET
(excluding major holidays)

Please see attached full Prescribing Information.
Please see Important Safety Information on page 14.

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Coverage

Novo Nordisk expects that Medicare, Medicaid, and almost all private insurance plans will cover NovoSeven for patients who meet the coverage criteria. However, some insurers may require prior authorization or submission of additional information with a claim before making a coverage decision. Examples of such materials include a package insert or letter of medical necessity.

Coding

To obtain adequate reimbursement for NovoSeven, providers must submit a properly coded claim form. Claims must include accurate codes for the following:

- Patient's diagnosis
- Physician procedures performed
- Units (micrograms or milligrams) of NovoSeven used

On the next two pages, you will find suggested codes to use for each of these categories. However, many insurers have unique coding and claims submission requirements. If you have any questions about how to bill appropriately for NovoSeven claims for a specific insurer, you may contact the insurer directly or call Novo Nordisk for assistance.

Diagnosis codes

All claim forms must include an International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) diagnosis code. It may be appropriate to use one of the diagnosis codes below for patients treated with NovoSeven Coagulation Factor VIIa (Recombinant).

If these diagnosis codes do not apply to your patient, please select the most appropriate code for use on the claim form.

286.0 Congenital factor VIII disorder

286.1 Congenital factor IX disorder

286.3 Congenital deficiency of other clotting factors (including FVII)

286.9 Other unspecified coagulation defects

Providers may also consider diagnosis codes that are specific to the hemorrhage site.

Providers should select the most appropriate code with the highest level of detail to describe a patient's condition.

Physician procedure codes

In addition to the diagnosis code, providers should submit the appropriate Current Procedural Terminology (CPT-4)* code to bill for the procedures involved in administering NovoSeven.

Providers may find the following codes applicable to this procedure:

Service	CPT code	Description
Infusion of Drug	90774	Therapeutic, prophylactic, or diagnostic injection; of drug intravenous (specify NovoSeven)
	90779	Unlisted therapeutic, prophylactic, or diagnostic injection (specify NovoSeven)

Drug codes

Providers may bill for NovoSeven using the following Healthcare Common Procedural Coding System (HCPCS) code:

Service	HCPCS code	Description
NovoSeven	J7189	Factor VIIa (Coagulation Factor, Recombinant) per 1 mcg equivalent

Additional codes for hospital-based procedures

If NovoSeven is administered in the hospital inpatient or outpatient setting, claims should also contain ICD-9-CM procedure codes and revenue codes as described below. The ICD-9-CM procedure codes used most commonly for the administration of NovoSeven are:

Hospital-based procedure	ICD-9-CM procedure code	Description
Infusion of Drug	99.06	Transfusion of coagulation factors / Transfusion of antihemophilic factor
	99.29	Injection or infusion of other therapeutic or prophylactic substance

Hospitals also use revenue codes to bill for supplies and services furnished to hospital inpatients and outpatients. Insurers may require NovoSeven to be billed with one of the following revenue codes:

Charge category	Revenue code	Description
Pharmacy	250	Pharmacy: general classification
Hospital Blood Service	380	Blood: general classification
	387	Blood: other derivatives
Drugs that require specific identification	636	Use of this code is reserved for drugs that require specific identification. This code is necessary when submitting Medicare claims for NovoSeven provided in a hospital

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Reimbursement

Inpatient hospital

Medicare, Medicaid, and many private payers reimburse for hospital inpatient services using a diagnosis-related group (DRG), case rate, or per diem system. Under these methodologies, insurers provide a fixed amount for each inpatient stay, and the cost of most drugs and supplies is included in this payment. However, Medicare provides separate reimbursement for hemophilia clotting factors provided to hospital inpatients.

Payment for NovoSeven may be based on the published Average Wholesale Price (AWP), however, Medicare will reimburse based on 106% of average sales price (ASP). To obtain payment, inpatient Medicare claims for NovoSeven must contain the following:

- Appropriate diagnosis code
- Revenue code 636
- HCPCS code J7189

Some Medicaid agencies and private payers also provide separate payment for blood clotting factors in the inpatient setting. Coding requirements will vary by insurer.

Outpatient hospital/Hemophilia treatment center

Most private insurers reimburse for outpatient services based on charges, discounted charges, costs, or per diem payments. Some private payers will reimburse for NovoSeven in addition to payment for services provided. Typically, insurers pay for a percentage of the allowed charge or cost. Patients are responsible for the remaining balance (coinsurance) or a flat copayment until they reach their maximum out-of-pocket expenditure, where applicable.

In August 2000, Medicare implemented an outpatient prospective payment system (OPPS) with billing based on the Ambulatory Payment Classifications (APCs) for hospital outpatient services. Under APCs, hospitals receive fixed payments for services provided. However, clotting factors are considered to be separately payable drugs, and in 2006, they will be reimbursed at 106% of ASP under the OPPS system. Additionally, clotting factors paid under Medicare Part B are subject to a "furnishing fee" that is paid in addition to the 106% of ASP. For 2006, CMS has calculated the blood clotting factor "furnishing fee" to be approximately $0.15 per unit. This will be in effect for all of 2006.

Home setting

Most private payers and Medicaid agencies reimburse for blood clotting factors used in the home. Claims must meet specific insurer guidelines, including substantiating medical necessity. The majority of private payers base reimbursement on AWP, Estimated Acquisition Cost (EAC), or a negotiated or contracted rate. In general, Medicare reimburses for blood clotting factors that are self-administered by hemophilia patients in the home. Payment is based on reasonable cost or reasonable charge, depending on the entity that dispenses the blood clotting factor.

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Claims processing

Be sure to complete your NovoSeven claim forms accurately (sample claims materials on pages 12 and 13). A HCFA-1450 (UB-92) claim form should be completed for hospital billing; a HCFA-1500 claim form is used when NovoSeven is administered in a physician's office or through a home health agency.

Establishing medical necessity and appealing denied claims

If you receive a denied claim for NovoSeven, you can often appeal the denial if the treatment was medically necessary. Please call 1-877-NOVO-777 (1-877-668-6777). The following steps provide general information about appealing denied claims.

Step 1: Review the denial

Review the Explanation of Benefits (EOB) sent by the insurer. Often claims are denied because of missing identification numbers, patient names, or signatures. Claims may also be denied for missing or improper codes. Correct any errors you identify and resubmit the claim.

Step 2: Resubmit the claim with more information

If you determine that the denial was not a result of claims submission errors, you may need to submit materials that document medical necessity. Resubmit the claim with a letter of medical necessity that highlights the following:

- Patient's medical history
- Other therapies that have been tried
- Reasons NovoSeven was prescribed for this particular patient
- Risks of forgoing NovoSeven treatment

In addition, you may wish to include the following information with the resubmitted claim:

- NovoSeven Coagulation Factor VIIa (Recombinant) package insert, which is included in the back of this brochure

Step 3: Appeal the denial

If a claim is denied a second time, please consider the following actions:

- Contact the claims manager or the medical director of the insurer to request a hearing or to file a grievance. Providers should be prepared to submit copies of claims and supporting documentation
- Encourage patients or their representatives to get involved

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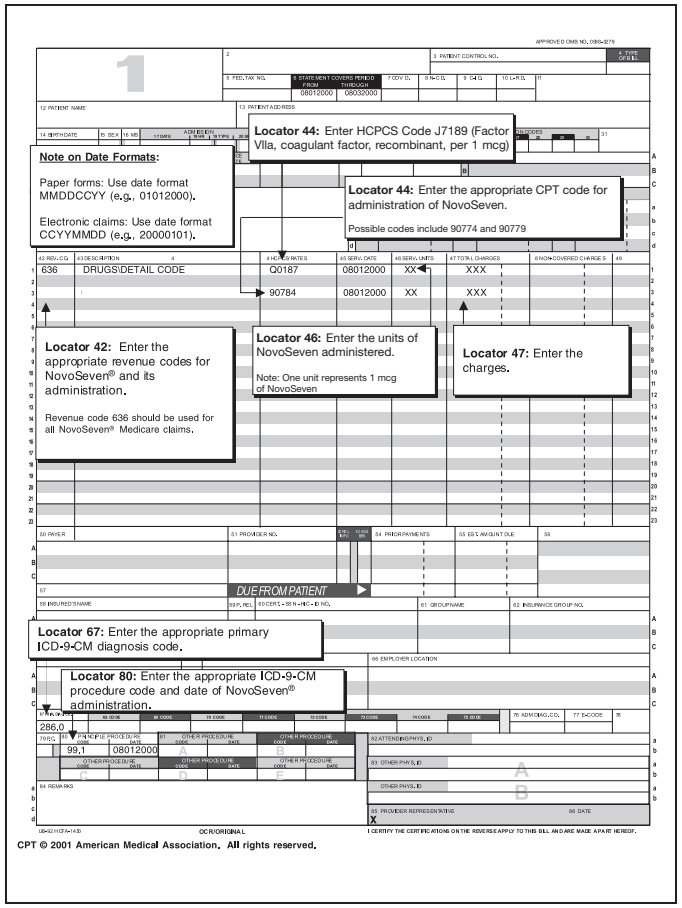
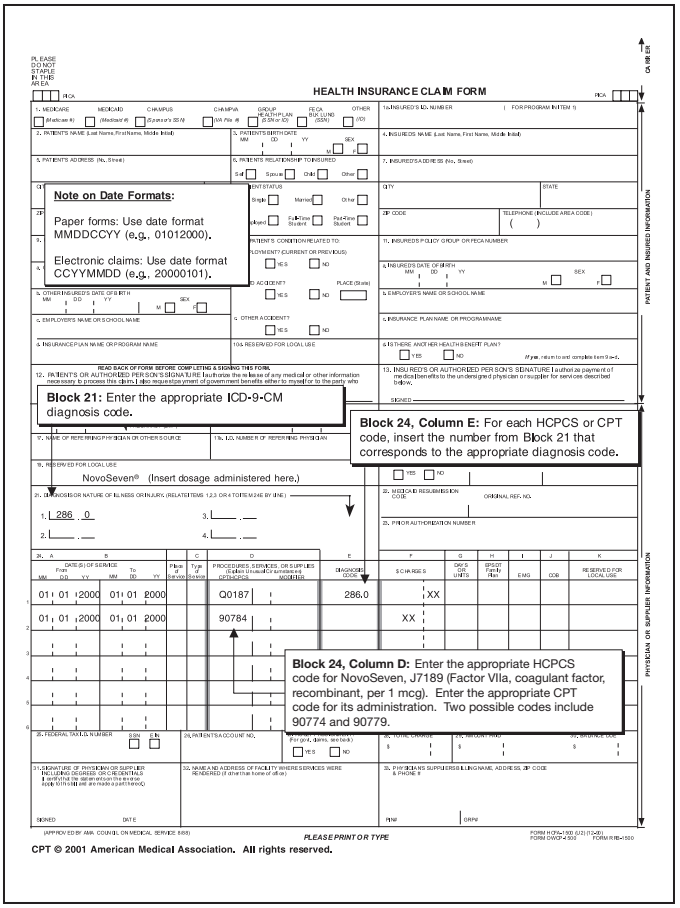
Claims Materials

Sample HCFA-1450 (UB-92) paper claim form for Medicare hospital NovoSeven billing



Sample HCFA-1500 paper claim form for physician, home health, and pharmacy NovoSeven billing



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Important Safety Information

- Most common adverse events: pyrexia, hemorrhage, injection site reaction, arthralgia, headache, hypertension, hypotension, nausea, vomiting, pain, edema, and rash
- Patients with disseminated intravascular coagulation (DIC), advanced atherosclerotic disease, crush injury, septicemia, or concomitant treatment with activated or nonactivated prothrombin complex concentrates (aPCCs/PCCs) may have a potential risk of developing thrombotic events in association with NovoSeven Coagulation Factor VIIa (Recombinant) treatment
- Contraindicated in patients with known hypersensitivity to NovoSeven or mouse, hamster, or bovine protein
- The risk of potential interaction between NovoSeven and coagulation factor concentrates has not been evaluated. Simultaneous use of aPCCs/PCCs should be avoided
- Disseminated intravascular coagulation (DIC) was reported in a few patients who received NovoSeven during treatment with aPCCs/PCCs
- Serious adverse events which may or may not have been related to the use of NovoSeven occurred in 14 of 298 patients in the initial clinical program
- Development of antibodies against Factor VII have been reported in Factor VII-deficient patients after treatment with NovoSeven. These patients had previously been treated with human plasma and/or plasma-derived Factor VII

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2 1/8 X 2 3/4

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This brochure is for educational purposes only. It is the provider's responsibility to ensure that accurate coding and documentation are provided to payers.

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