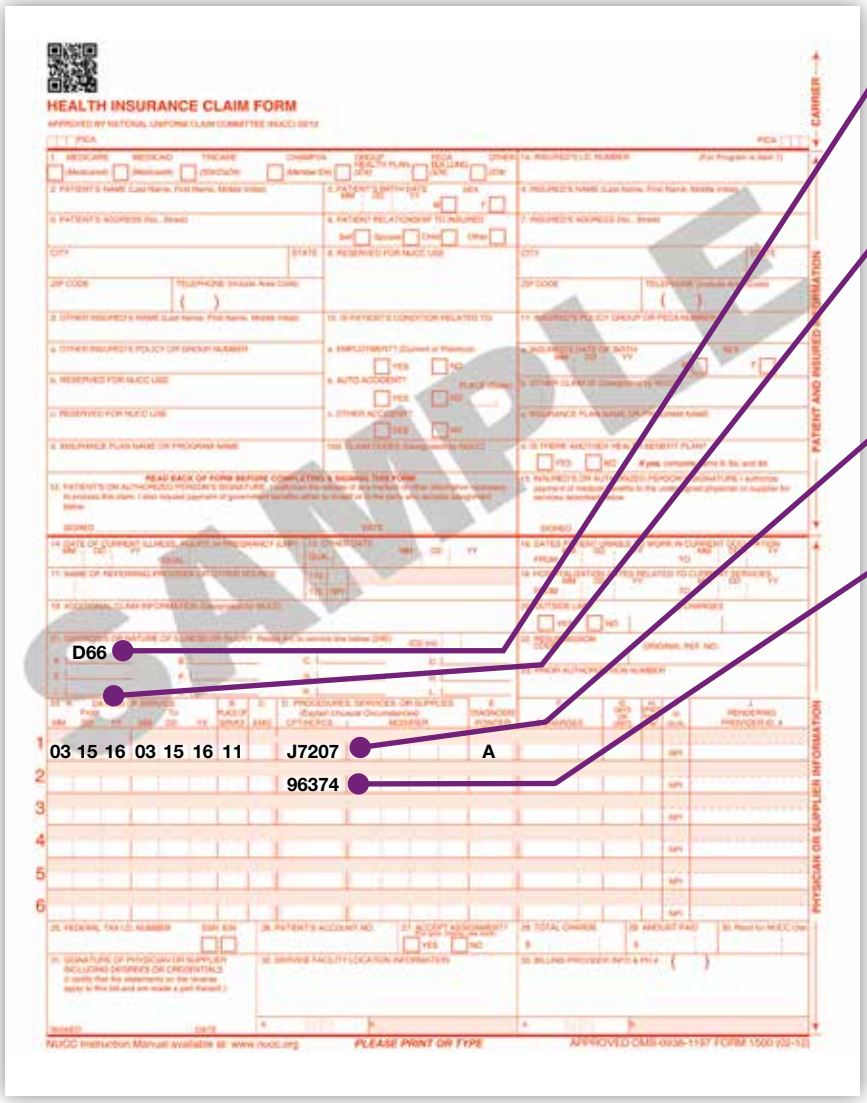
Sample CMS-1500 Claim Form for ADYNOVATE®

Physician Office Setting

ADYNOVATE
[Antihemophilic Factor (Recombinant), PEGylated]

Claims within this form must include the following information, as indicated on the example form shown below:

- Patient diagnosis code(s)
- Physician procedure code(s)
- Drug code(s)



The ICD-10 code is entered in **Box 21**.
The code for hereditary factor VIII deficiency is D66.

Box 24: Medicaid and some commercial payers require the NDC number to be written in the shaded portion of the line item in fields 24A-24G. Next, the following should be entered: 1 space for separation, followed by the appropriate qualifier for the dispensing unit of measure, followed by the quantity (number of units up to 3 decimal places), 1 space, and the price per unit.[1]

Box 24D, Line 1: Add the appropriate HCPCS Reimbursement Code for ADYNOVATE:

- J7207 ADYNOVATE [Antihemophilic Factor (Recombinant), PEGylated]

Box 24D, Line 2: Insert the required administration code or CPT code. All administration codes need to be billed on a separate line.

CPT® Code	Description
96374	Intravenous (IV) push, single or initial substance or drug
96376*	Each additional sequential IV push of the same substance/drug provided in a facility

*Do not report 96376 for a push performed within 30 minutes of a reported push of the same substance or drug; 96376 may be reported by facilities only.

NDC Number[2] (Includes sWFI Diluent)	Nominal Strength	Actual Factor VIII Potency Range
0944-4622-01	250 IU	200-400 IU per vial
0944-4623-01	500 IU	401-800 IU per vial
0944-4626-01	750 IU	600-940 IU per vial
0944-4624-01	1000 IU	801-1250 IU per vial
0944-4627-01	1500 IU	1200-1875 IU per vial
0944-4625-01	2000 IU	1251-2500 IU per vial

CMS-1500 forms can be obtained at:
https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/CMS1500.pdf

The information contained in this CMS-1500 Guide is provided for informational purposes only. Every reasonable effort has been made to verify the accuracy of the information as of December 2016; however, this guide is not intended to provide specific guidance on how to utilize codes, bill, or charge for any product or service. Healthcare providers make the ultimate determination of product use based on clinical need. Third-party payment for medical products and services is affected by numerous factors, and Shire cannot guarantee success in obtaining insurance payments.

Please see the ADYNOVATE Indications and Detailed Important Risk Information on page 2.
Please click here for the ADYNOVATE full Prescribing Information.

Shire

ADYNOVATE
[Antihemophilic Factor (Recombinant), PEGylated]

ADYNOVATE [Antihemophilic Factor (Recombinant), PEGylated] Important Information

Indications

ADYNOVATE, Antihemophilic Factor (Recombinant), PEGylated, is a human antihemophilic factor indicated in children and adults with hemophilia A (congenital factor VIII deficiency) for:

- On-demand treatment and control of bleeding episodes
- Perioperative management
- Routine prophylaxis to reduce the frequency of bleeding episodes

Limitation of Use

ADYNOVATE is not indicated for the treatment of von Willebrand disease.

DETAILED IMPORTANT RISK INFORMATION

CONTRAINDICATIONS

ADYNOVATE is contraindicated in patients who have had prior anaphylactic reaction to ADYNOVATE, to the parent molecule (ADVATE [Antihemophilic Factor (Recombinant)]), mouse or hamster protein, or excipients of ADYNOVATE (e.g. Tris, mannitol, trehalose, glutathione, and/or polysorbate 80).

WARNINGS & PRECAUTIONS

Hypersensitivity Reactions

Hypersensitivity reactions are possible with ADYNOVATE. Allergic-type hypersensitivity reactions, including anaphylaxis, have been reported with other recombinant antihemophilic factor VIII products, including the parent molecule, ADVATE. Early signs of hypersensitivity reactions that can progress to anaphylaxis may include angioedema, chest tightness, dyspnea, wheezing, urticaria, and pruritus. Immediately discontinue administration and initiate appropriate treatment if hypersensitivity reactions occur.

Neutralizing Antibodies

Formation of neutralizing antibodies (inhibitors) to factor VIII can occur following administration of ADYNOVATE. Monitor patients regularly for the development of factor VIII inhibitors by appropriate clinical observations and laboratory tests. Perform an assay that measures factor VIII inhibitor concentration if the plasma factor VIII level fails to increase as expected, or if bleeding is not controlled with expected dose.

ADVERSE REACTIONS

The most common adverse reactions (≥1% of subjects) reported in the clinical studies were headache and nausea.

Please click here for the ADYNOVATE full Prescribing Information.

References: 1. Centers for Medicare and Medicaid Services. Transmittal 1401. https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R1401CP.pdf. Accessed December 5, 2016. **2.** ADYNOVATE Prescribing Information.

For information on Shire reimbursement assistance or support, call 1-855-229-7377.

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