Gadavist® (gadobutrol) Injection Coding Tip Sheet

Freestanding Outpatient Facilities

Billing for Gadavist

Healthcare Common Procedure Coding System (HCPCS) code A9585 has been established by the Centers for Medicare and Medicaid Services (CMS) for Gadavist.[1] CMS sought to assign a code which would allow for accurate billing of all Gadavist presentations. This code was made available to all payers on January 1, 2012.

HCPCS Code for Use with Gadavist

HCPCS code	A9585
Code description	Injection, Gadobutrol, 0.1 mL

The code descriptor for A9585 is per 0.1 mL. When billing it is important to remember to **multiply the amount of Gadavist used by 10 in order to list the correct number of units on the claim form.**

- 2 mL = 20 units
- 7.5 mL = 75 units
- 10 mL = 100 units
- 15 mL = 150 units

This is different from using other contrast codes which are designated as per 1 mL. By assigning the lower mL designation, CMS allows providers to accurately capture the appropriate amount of Gadavist used and reduce the potential for over- or under-billing.

- To avoid billing confusion, the use of Gadavist should be noted on the patient's report dictated by the radiologist

Note: The Centers for Medicare & Medicaid Services states that drugs and biologicals, including contrast material, approved after 2003 are eligible to receive unique and specific codes.[2] Bayer has received a specific HCPCS code for Gadavist effective January 2012.

Indications and Usage

Gadavist® (gadobutrol) injection is a gadolinium-based contrast agent indicated for use with magnetic resonance imaging (MRI):

- To detect and visualize areas with disrupted blood brain barrier (BBB) and/or abnormal vascularity of the central nervous system in adult and pediatric patients (including term neonates)
- To assess the presence and extent of malignant breast disease

Gadavist® is indicated for use in magnetic resonance angiography (MRA):

- To evaluate known or suspected supra-aortic or renal artery disease in adult and pediatric patients (including term neonates)

Important Safety Information

WARNING: NEPHROGENIC SYSTEMIC FIBROSIS (NSF)

Gadolinium-based contrast agents (GBCAs) increase the risk for NSF among patients with impaired elimination of the drugs. Avoid use of GBCAs in these patients unless the diagnostic information is essential and not available with non-contrasted MRI or other modalities. NSF may result in fatal or debilitating fibrosis affecting the skin, muscle and internal organs.

- The risk of NSF appears highest among patients with:
  - Chronic, severe kidney disease (GFR <30 mL/min/1.73m^2), or
  - Acute kidney injury
- Screen patients for acute kidney injury and other conditions that may reduce renal function. For patients at risk for chronically reduced renal function (for example, age >60 years, hypertension or diabetes), estimate the glomerular filtration rate (GFR) through laboratory testing.
- For patients at highest risk for NSF, do not exceed the recommended GADAVIST dose and allow a sufficient period of time for elimination of the drug from the body prior to any re-administration.

Please see additional Important Safety Information throughout this piece.

Please click here to see the Gadavist® Full Prescribing Information (Vials & Syringes).

Please click here to see the Gadavist® Full Prescribing Information (Pharmacy Bulk Package).

Learn more about Gadavist at gadavist.com

Gadavist®
(gadobutrol) injection
1 mmol/mL

Reimbursement for Contrast by Payer

Medicare: Local Medicare contractors reimburse separately for non-oral contrast material when it is used with a procedure.

Private Commercial: Some managed care organizations reimburse separately for contrast when billed with a procedure. Please consult the Reimbursement Helpline for guidance.

Under Medicare, freestanding providers can bill for waste. If a provider opens a 10 mL vial and uses only 8 mL, they may bill for the additional 2 mL by using a JW modifier in the appropriate location on the claim form. Please contact your Medicare Administrative Carrier or the Bayer Imaging Reimbursement Helpline for details.

The Bayer Imaging Reimbursement Helpline is available to all institutions to provide further information on Gadavist coverage reimbursement.

The Helpline can be reached at 800-423-7539 or via email at imaging@prgweb.com.

Information provided in this resource is for informational purpose only and does not guarantee that codes will be appropriate or that coverage and reimbursement will result. Customers should consult with their payers for all relevant coverage, coding, and reimbursement requirements. It is the sole responsibility of the provider to select proper codes and ensure the accuracy of all claims used in seeking reimbursement. Neither this resource nor the Bayer Healthcare Reimbursement Helpline is intended as a legal advice or as a substitute for a provider's independent professional judgment.

Important Safety Information (continued)

Contraindication and Important Information about Hypersensitivity Reactions: Gadavist® is contraindicated in patients with history of severe hypersensitivity reactions to Gadavist®. Anaphylactic and other hypersensitivity reactions with cardiovascular, respiratory, or cutaneous manifestations, ranging from mild to severe, including death, have uncommonly occurred following Gadavist® administration. Before Gadavist® administration, assess all patients for any history of a reaction to contrast media, bronchial asthma and/or allergic disorders. These patients may have an increased risk for a hypersensitivity reaction to Gadavist®.

Acute Kidney Injury: In patients with chronic renal impairment, acute kidney injury sometimes requiring dialysis has been observed with the use of some GBCAs. Do not exceed the recommended dose; the risk of acute kidney injury may increase with higher than recommended doses.

Extravasation and Injection Site Reactions: Ensure catheter and venous patency before the injection of Gadavist®. Extravasation into tissues during Gadavist® administration may result in moderate irritation.

Overestimation of Extent of Malignant Disease in MRI of the Breast: Gadavist® MRI of the breast overestimated the histologically confirmed extent of malignancy in the diseased breast in up to 50% of the patients.

Please see additional Important Safety Information throughout this piece.

Gadavist®
(gadobutrol) injection
1 mmol/mL

Claim Form Guidance

To help demonstrate billing of Gadavist® (gadobutrol) injection, the sample claim below is provided:

1500

HEALTH INSURANCE CLAIM FORM

APPROVED BY NATIONAL UNIFORM CLAIM COMMITTEE 08/05

PICA

1. MEDICARE (Medicare #) MEDICAID (Medicaid #) TRICARE CHAMPUS (Sponsor's SSN) CHAMPVA (Member ID#) GROUP HEALTH PLAN (SSN or ID) FECA BLK LUNG (SSN) OTHER (ID)

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

8. PATIENT STATUS Single Married Other Employed Full-Time Student Part-Time Student

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)

10. IS PATIENT'S CONDITION RELATED TO:

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 SEX M F

b. OTHER INSURED'S DATE OF BIRTH MM DD YY SEX M F

b. AUTO ACCIDENT? YES NO PLACE (State)

b. EMPLOYER'S NAME OR SCHOOL NAME

c. EMPLOYER'S NAME OR SCHOOL NAME

c. OTHER ACCIDENT? YES NO

c. INSURANCE PLAN NAME OR PROGRAM NAME

d. INSURANCE PLAN NAME OR PROGRAM NAME

10d. RESERVED FOR LOCAL USE

d. IS THERE ANOTHER HEALTH BENEFIT PLAN? YES NO *If yes*, return to and complete item 9 a-d.

READ BACK OF FORM BEFORE COMPLETING & SIGNING THIS FORM.

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

13. INSURED'S OR AUTHORIZED PERSON'S SIGNATURE I authorize payment of medical benefits to the undersigned physician or supplier for services described below.

SIGNED

14. DATE OF CURRENT: MM DD YY ILLNESS (First symptom) OR INJURY (Accident) OR PREGNANCY(LMP)

15. IF PATIENT HAS HAD SAME OR SIMILAR ILLNESS, GIVE FIRST DATE MM DD YY

16. DATES PATIENT UNABLE TO WORK IN CURRENT OCCUPATION MM DD YY FROM TO MM DD YY

17. NAME OF REFERRING PROVIDER OR OTHER SOURCE

17a.

17b. NPI

18. HOSPITALIZATION DATES RELATED TO CURRENT SERVICES MM DD YY FROM TO MM DD YY

19. RESERVED FOR LOCAL USE

Gadavist (gadobutrol) injection

20. OUTSIDE LAB? YES NO $ CHARGES

21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY (Relate Items 1, 2, 3 or 4 to Item 24E by Line)

1. 3.

2. 4.

22. MEDICAID RESUBMISSION CODE ORIGINAL REF. NO.

23. PRIOR AUTHORIZATION NUMBER

24. A. DATE(S) OF SERVICE From MM DD YY	To MM DD YY	B. PLACE OF SERVICE	C. EMG	D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) CPT/HCPCS	MODIFIER	E. DIAGNOSIS POINTER	F. $ CHARGES	G. DAYS OR UNITS	H. EPSDT Family Plan	I. ID. QUAL.	J. RENDERING PROVIDER ID. #
1	02 01 12	02 01 12			A9585		XX	XX 100			NPI
2	02 01 12	02 01 12			70552*						NPI
3											NPI
4											NPI
5											NPI
6											NPI

25. FEDERAL TAX I.D. NUMBER SSN EIN

26. PATIENT'S ACCOUNT NO.

27. ACCEPT ASSIGNMENT? (For govt. claims, see back) YES NO

28. TOTAL CHARGE $

29. AMOUNT PAID $

30. BALANCE DUE $

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.)

SIGNED DATE

32. SERVICE FACILITY LOCATION INFORMATION

a. NPI b.

33. BILLING PROVIDER INFO & PH # ( )

a. NPI b.

NUCC Instruction Manual available at: www.nucc.org

APPROVED OMB-0938-0999 FORM CMS-1500 (08/05)

CARRIER

PATIENT AND INSURED INFORMATION

PHYSICIAN OR SUPPLIER INFORMATION

Full name of drug

HCPCS code for product—Gadavist A9585

Dollar amount billed for Gadavist

Enter quantity—because the HCPCS code is per 0.1 mL, the actual amount of Gadavist used should be multiplied by 10 to ensure that providers submit accurate claims. This claim form example reflects the correct way to bill for administering 10 mL of Gadavist.

Important Safety Information (continued)

Low Sensitivity for Significant Arterial Stenosis: The performance of Gadavist® MRA for detecting arterial segments with significant stenosis (>50% renal, >70% supra-aortic) has not been shown to exceed 55%. Therefore, a negative MRA study alone should not be used to rule out significant stenosis.

Adverse Reactions: The most frequent (≥0.5%) adverse reactions associated with Gadavist® in clinical studies were headache (1.5%), nausea (1.1%) and dizziness (0.5%).

Please see additional Important Safety Information throughout this piece.

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References: 1. http://downloads.cms.gov/medicare-coverage-database/lcd_attachments/28723_79/L28723_RAD024_CBG_060112.pdf. August 16, 2016.
2. https://www.cms.gov/medicare/coding/medhcpcsgeninfo/downloads/051807_coding_annoucement.pdf. August 16, 2016.

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