Aduhelm™ (aducanumab-avwa) | 100 mg/mL solution for infusion

Relevant Codes and Sample Claim Forms Guide

INDICATION

ADUHELM is indicated for the treatment of Alzheimer's disease. This indication is approved under accelerated approval based on reduction in amyloid beta plaques observed in patients treated with ADUHELM. Continued approval for this indication may be contingent upon verification of clinical benefit in confirmatory trial(s).

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

Amyloid Related Imaging Abnormalities

- ADUHELM can cause amyloid related imaging abnormalities-edema (ARIA-E), which can be observed on MRI as brain edema or sulcal effusions, and amyloid related imaging abnormalities-hemosiderin deposition (ARIA-H), which includes microhemorrhage and superficial siderosis
- Obtain recent (within one year) brain magnetic resonance imaging (MRI) prior to initiating treatment. The safety of ADUHELM in patients with any pre-treatment localized superficial siderosis, 10 or more brain microhemorrhages, and/or with a brain hemorrhage greater than 1 cm within one year of treatment initiation has not been established
- In clinical studies of ADUHELM, the severity of ARIA was classified by radiographic criteria. **Mild ARIA-E:** FLAIR hyperintensity confined to sulcus and or cortex/subcortical white matter in one location < 5 cm. **Moderate ARIA-E:** FLAIR hyperintensity 5 to 10 cm, or more than 1 site of involvement, each measuring < 10 cm. **Severe ARIA-E:** FLAIR hyperintensity measuring > 10 cm, often with significant subcortical white matter and/or sulcal involvement. One or more separate sites of involvement may be noted. **Mild ARIA-H microhemorrhage:** ≤ 4 new incident microhemorrhages. **Moderate ARIA-H microhemorrhage:** 5 to 9 new incident microhemorrhages. **Severe ARIA-H microhemorrhage:** 10 or more new incident microhemorrhages. **Mild ARIA-H superficial siderosis:** 1 focal area of superficial siderosis. **Moderate ARIA-H superficial siderosis:** 2 focal areas of superficial siderosis. **Severe ARIA-H superficial siderosis:** > 2 focal areas of superficial siderosis
- In Studies 1 and 2, ARIA (-E and/or -H) was observed in 41% of patients treated with ADUHELM with a planned dose of 10 mg/kg (454 out of 1105), compared to 10% of patients on placebo (111 out of 1087)
- ARIA-E was observed in 35% of patients treated with ADUHELM 10 mg/kg, compared to 3% of patients on placebo. The incidence of ARIA-E was higher in apolipoprotein E ε4 (ApoE ε4) carriers than in ApoE ε4 non-carriers (42% and 20%, respectively). The majority of ARIA-E radiographic events occurred early in treatment (within the first 8 doses), although ARIA can occur at any time. Among patients treated with a planned dose of ADUHELM 10 mg/kg who had ARIA-E, the maximum radiographic severity was mild in 30%, moderate in 58%, and severe in 13% of patients. Resolution occurred in 68% of ARIA-E patients by 12 weeks, 91% by 20 weeks, and 98% overall after detection. 10% of all patients who received ADUHELM 10 mg/kg had more than one episode of ARIA-E

Please see additional Important Safety Information throughout and full Prescribing Information.

Sample Diagnosis and Product Codes for ADUHELM™ (aducanumab-avwa)

ADUHELM is indicated for the treatment of Alzheimer's disease. This indication is approved under accelerated approval based on reduction in amyloid beta plaques observed in patients treated with ADUHELM. Continued approval for this indication may be contingent upon verification of clinical benefit in confirmatory trial(s).

G30.0: Alzheimer's disease with early onset[1*]

or

G30.1: Alzheimer's disease with late onset[2*]

or

G30.8: Other Alzheimer's disease[3*]

or

G31.84: Mild cognitive impairment, so stated[4†]

+ Either

F02.80 Dementia without behavioral disturbance[5]

or

F02.81 Dementia with behavioral disturbance[6]

Location on CMS-1500 Payer Form (Electronic Equivalent)[7]
Field 21 (Loop: 2300; Segment: HI01-2)

Location on CMS-1450/UB-04 Form (Electronic Equivalent)[8]
Field 67 (Loop: 2300; Segment: HI01-2)

*When coding Alzheimer's disease, also code to identify the patient's dementia; there are currently no codes to specify mild, moderate, or severe dementia. F02.80 and F02.81 can only be utilized with either G30.0, G.30.1, or G30.8.
†There are no specific codes currently available for a diagnosis of mild cognitive impairment due to Alzheimer's disease.

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

Amyloid Related Imaging Abnormalities (cont'd)

- ARIA-H in the setting of ARIA-E associated with the use of ADUHELM 10 mg/kg was observed in 21% of patients treated with ADUHELM 10 mg/kg, compared to 1% of patients on placebo. There was no imbalance in isolated ARIA-H (i.e., ARIA-H in patients who did not also experience ARIA-E) between ADUHELM and placebo. There was no imbalance in hemorrhage greater than 1 cm between ADUHELM and placebo
- Clinical symptoms were present in 24% of patients treated with ADUHELM 10 mg/kg who had an observation of ARIA (-E and/or -H), compared to 5% of patients on placebo. The most common symptom in patients treated with ADUHELM 10 mg/kg with ARIA was headache (13%). Other frequent symptoms were confusion/delirium/altered mental status/disorientation (5%), dizziness/vertigo (4%), visual disturbance (2%), and nausea (2%). Serious symptoms associated with ARIA were reported in 0.3% of patients treated with ADUHELM 10 mg/kg. Clinical symptoms resolved in the majority of patients (88%) during the period of observation
- Enhanced clinical vigilance for ARIA is recommended during the first 8 doses of treatment with ADUHELM, particularly during titration, as this is the time the majority of ARIA was observed in Studies 1 and 2. If a patient experiences symptoms which could be suggestive of ARIA, clinical evaluation should be performed, including MRI testing if indicated. If ARIA is observed on MRI in the presence of clinical symptoms, careful clinical evaluation should be performed prior to continuing treatment
- Obtain brain MRIs prior to the 7th infusion (first dose of 10 mg/kg) and 12th infusion (sixth dose of 10 mg/kg) of ADUHELM to evaluate for the presence of asymptomatic ARIA. For patients with radiographic findings of ARIA, enhanced clinical vigilance is recommended. Additional MRIs may be considered if clinically indicated. If radiographically severe ARIA-H is observed, treatment may be continued with caution only after a clinical evaluation and a follow-up MRI demonstrates radiographic stabilization (i.e., no increase in size or number of ARIA-H). For ARIA-E or mild/moderate ARIA-H, treatment may continue with caution. If dosing is temporarily suspended, dosing may resume at that same dose and titration schedule. There are no systematic data on continued dosing with ADUHELM following detection of radiographically moderate or severe ARIA. In Studies 1 and 2, temporary dose suspension was required for radiographically moderate or severe ARIA-E and radiographically moderate ARIA-H. In Studies 1 and 2, permanent discontinuation of dosing was required for radiographically severe ARIA-H. The benefits of reaching and maintaining the 10 mg/kg dose should be considered when evaluating a potential dose suspension

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HCPCS Codes for ADUHELM™ (aducanumab-avwa)*

Coding System	Code (Description)[9,10]	Location on CMS-1500 Payer Form (Electronic Equivalent)[7]	Location on CMS-1450/ UB-04 Form (Electronic Equivalent)[8]	Comments
HCPCS	J3590: Unclassified biologics C9399: Unclassified drugs or biologicals	Field 24D (Loop: 2400; Segment: SV101)	Field 44 (Loop: 2400; Segment: SV202)	When completing the CMS-1500 form, use Field 19 to include details about product dosing, such as drug name, NDC number, and number of units. In the case of a Medicare hospital outpatient claim, you may be required to use a miscellaneous C-code (C9399) rather than a J-code.
	Number of units	Field 24G (Loop: 2400; Segment: SV104)	Field 46 (Loop: 2400; Segment: SV205)	Include the number of units for the service date.

CMS=Centers for Medicare & Medicaid Services; HCPCS=Healthcare Common Procedure Coding System; NDC=National Drug Code; SP=specialty pharmacy.
*If you order ADUHELM through an SP, you will not need to submit a claim for reimbursement for the product; however, you will have to submit a claim for reimbursement for services associated with ADUHELM.

NDC Codes for ADUHELM

Coding System	Code (Description)[11]	Location on CMS-1500 Payer Form (Electronic Equivalent)	Location on CMS-1450/ UB-04 Form (Electronic Equivalent)	Comments
NDC	64406-101-01—170 mg/1.7 mL (100 mg/mL) single-dose vial	Per payer requirements	Per payer requirements	Although the FDA uses a 10-digit format when registering NDCs, payers often require an 11-digit NDC format on claim forms for billing purposes. The 10-digit ADUHELM format is converted to an 11-digit code by adding a zero (0) in front of the second group of numbers, eg, 64406-0101-01. It is important to communicate with your payers to determine the appropriate NDC format requirements.
	64406-102-02—300 mg/3 mL (100 mg/mL) single-dose vial			

FDA=US Food and Drug Administration.

All coding and documentation requirements should be confirmed with each payer before submitting a claim for reimbursement.

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

Hypersensitivty Reactions

- Angioedema and urticaria were reported in one patient in the placebo-controlled period of Studies 1 and 2, and occurred during the ADUHELM infusion. Promptly discontinue the infusion upon the first observation of any signs or symptoms consistent with a hypersensitivity reaction, and initiate appropriate therapy

NDC Codes for ADUHELM™ (aducanumab-avwa) (cont'd)

ADUHELM is designated by a miscellaneous J-code (also referred to as unclassified J-code or Not Otherwise Classified [NOC] J-code) or a miscellaneous C-code. The miscellaneous code should be used until a permanent code is assigned.

When submitting a claim with an NOC J-code, payers typically require supplemental product information for manual claims processing, such as the *drug name, 11-digit NDC number, concentration, amount administered, and route of administration*; however, specific requirements may vary by payer and should be reviewed prior to submitting a claim.

Guidelines for reporting the NDC number in the appropriate format, quantity, and unit of measure vary by state and by payer and should be reviewed prior to submitting a claim.

Use of JW Modifier for Drug/Biological Amount Discarded or Not Administered[12]

- HCPs are required to report the JW modifier on Part B drug claims for discarded drugs and biologicals, as well as document the amount of discarded drugs or biologicals in a Medicare patient's records
- The discarded amount is defined as what remains from a single-use vial or other single-use packaging after administering a dose or quantity of drug to a Medicare patient
- The JW modifier is used on Part B claims to report the amount of drug discarded that is eligible for payment under the discarded drug policy. It must be used in order to be eligible for payment

For additional information on use of the JW modifier, the Centers for Medicare & Medicaid Services has developed a Frequently Asked Questions resource available at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/JW-Modifier-FAQs.pdf.

Accurate coding is important to receive timely reimbursement for ADUHELM and associated administration services. It is important to confirm codes prior to administering to help ensure that the insurance plan will pay for both the drug itself and associated services, as applicable.

IMPORTANT SAFETY INFORMATION (cont'd)

ADVERSE REACTIONS

- In the combined placebo-controlled and long-term extension periods, 5% (66 out of 1386) of patients in the 10 mg/kg dose group withdrew from the study because of an adverse reaction. The most common adverse reaction resulting in study withdrawal in the combined placebo-controlled and long-term extension periods was ARIA-H superficial siderosis
- The most common adverse reactions reported in at least 2% of patients treated with ADUHELM 10 mg/kg and at least 2% more frequently than in patients on placebo in Studies 1 and 2 were ARIA-E (35% ADUHELM vs. 3% placebo), headache (21% ADUHELM vs. 16% placebo), ARIA-H microhemorrhage (19% ADUHELM vs. 7% placebo), ARIA-H superficial siderosis (15% ADUHELM vs. 2% placebo), fall (15% ADUHELM vs. 12% placebo), diarrhea (9% ADUHELM vs. 7% placebo), and confusion/delirium/altered mental status/disorientation (8% ADUHELM vs. 4% placebo)

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Administration Codes for ADUHELM™ (aducanumab-avwa)

Product Administration—Intravenous (IV) Infusion

One unit with code 96413 or 96365 may be used to report the time from the start of the infusion until 60 minutes into the infusion.

Coding System	Code (Description)[13]	Location on CMS-1500 Payer Form (Electronic Equivalent)[7]	Location on CMS-1450/ UB-04 Form (Electronic Equivalent)[8]
CPT®	**96413** - Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance drug; also applies to certain monoclonal antibody agents and biologic response modifiers **96415** - each additional hour, up to 91 minutes (List separately in addition to code for primary procedure)	Field 24D (Loop: 2400; Segment: SV101)	Field 44 (Loop: 2400; Segment: SV202)
	96365 - Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); initial, up to 1 hour **96366** - each additional hour (List separately in addition to code for primary procedure)	Field 24D (Loop: 2400; Segment: SV101)	Field 44 (Loop: 2400; Segment: SV202)
	Enter the number of units	Field 24G (Loop: 2400; Segment: SV104)	Field 46 (Loop: 2400; Segment: SV205)

CPT=Current Procedural Terminology.

Typically, administration of ADUHELM requires approximately 1 hour of infusion. The total number of hours (from when the medication starts dripping until it stops) is reported in Field 24G (electronic equivalent—Loop: 2400; Segment: SV104).

IMPORTANT: When documenting the start and stop time for the drug infusion, do not include any time when the IV is running to keep the line open, or TKO.

IMPORTANT SAFETY INFORMATION (cont'd)

ADVERSE REACTIONS (cont'd)

- Immunogenicity: The immunogenicity of ADUHELM has been evaluated using an in vitro assay for the detection of binding anti-aducanumab-avwa antibodies. In up to 41 months of treatment in the combined placebo-controlled and long-term extension periods of Studies 1 and 2, up to 0.6% (15/2689) of patients receiving ADUHELM once monthly developed anti-aducanumab-avwa antibodies. Based on the limited number of patients who tested positive for anti-aducanumab-avwa antibodies, no observations were made concerning a potential effect of neutralizing activity of anti-aducanumab-avwa antibodies on exposure or efficacy; however, the available data are too limited to make definitive conclusions regarding an effect on pharmacokinetics, safety, or efficacy of ADUHELM. Quantification of neutralizing anti-aducanumab-avwa antibodies has not been assessed

These codes are presented for informational purposes only and do not guarantee reimbursement. All coding and documentation requirements should be confirmed with each payer before submitting a claim for reimbursement.

Evaluation and Management Codes

In some instances, you may provide an evaluation and management (E/M) service in addition to the infusion within the physician office/clinic or during the hospital outpatient visit. A separate and identifiable procedure must be performed in order to bill for an E/M service in addition to the drug infusion. To bill for both services, the additional service must be clearly documented in the patient's medical record. Some payers may also require the use of the -25 modifier, which tells the payer that the additional services were performed within the same visit.[14]

If the payer allows you to bill for an E/M code in addition to the drug infusion, there are many factors that you should consider in determining which E/M code to use[14]:

- **Patient status (new or established)**
- **Level of decision-making required**
- **Complexity of the case**
- **Time spent with the patient**

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

Amyloid Related Imaging Abnormalities

- ADUHELM can cause amyloid related imaging abnormalities-edema (ARIA-E), which can be observed on MRI as brain edema or sulcal effusions, and amyloid related imaging abnormalities-hemosiderin deposition (ARIA-H), which includes microhemorrhage and superficial siderosis
- Obtain recent (within one year) brain magnetic resonance imaging (MRI) prior to initiating treatment. The safety of ADUHELM in patients with any pre-treatment localized superficial siderosis, 10 or more brain microhemorrhages, and/or with a brain hemorrhage greater than 1 cm within one year of treatment initiation has not been established
- In clinical studies of ADUHELM, the severity of ARIA was classified by radiographic criteria. **Mild ARIA-E:** FLAIR hyperintensity confined to sulcus and or cortex/subcortical white matter in one location < 5 cm. **Moderate ARIA-E:** FLAIR hyperintensity 5 to 10 cm, or more than 1 site of involvement, each measuring < 10 cm. **Severe ARIA-E:** FLAIR hyperintensity measuring > 10 cm, often with significant subcortical white matter and/or sulcal involvement. One or more separate sites of involvement may be noted. **Mild ARIA-H microhemorrhage:** ≤ 4 new incident microhemorrhages. **Moderate ARIA-H microhemorrhage:** 5 to 9 new incident microhemorrhages. **Severe ARIA-H microhemorrhage:** 10 or more new incident microhemorrhages. **Mild ARIA-H superficial siderosis:** 1 focal area of superficial siderosis. **Moderate ARIA-H superficial siderosis:** 2 focal areas of superficial siderosis. **Severe ARIA-H superficial siderosis:** > 2 focal areas of superficial siderosis
- In Studies 1 and 2, ARIA (-E and/or -H) was observed in 41% of patients treated with ADUHELM with a planned dose of 10 mg/kg (454 out of 1105), compared to 10% of patients on placebo (111 out of 1087).
- ARIA-E was observed in 35% of patients treated with ADUHELM 10 mg/kg, compared to 3% of patients on placebo. The incidence of ARIA-E was higher in apolipoprotein E ε4 (ApoE ε4) carriers than in ApoE ε4 non-carriers (42% and 20%, respectively). The majority of ARIA-E radiographic events occurred early in treatment (within the first 8 doses), although ARIA can occur at any time. Among patients treated with a planned dose of ADUHELM 10 mg/kg who had ARIA-E, the maximum radiographic severity was mild in 30%, moderate in 58%, and severe in 13% of patients. Resolution occurred in 68% of ARIA-E patients by 12 weeks, 91% by 20 weeks, and 98% overall after detection. 10% of all patients who received ADUHELM 10 mg/kg had more than one episode of ARIA-E

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E/M Codes for New Patients

Coding System	Code and Description[13]
CPT®	**99202** - E/M of a new patient, which requires a medically appropriate history and/or examination and straightforward medical decision-making When using time for code selection, 15-29 minutes of total time is spent on the date of the encounter **99203** - E/M of a new patient, which requires a medically appropriate history and/or examination and low level of medical decision-making When using time for code selection, 30-44 minutes of total time is spent on the date of the encounter **99204** - E/M of a new patient, which requires a medically appropriate history and/or examination and moderate level of medical decision-making When using time for code selection, 45-59 minutes of total time is spent on the date of the encounter **99205** - E/M of a new patient, which requires a medically appropriate history and/or examination and high level of medical decision-making When using time for code selection, 60-74 minutes of total time is spent on the date of the encounter

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

Amyloid Related Imaging Abnormalities (cont'd)

- ARIA-H in the setting of ARIA-E associated with the use of ADUHELM 10 mg/kg was observed in 21% of patients treated with ADUHELM 10 mg/kg, compared to 1% of patients on placebo. There was no imbalance in isolated ARIA-H (i.e., ARIA-H in patients who did not also experience ARIA-E) between ADUHELM and placebo. There was no imbalance in hemorrhage greater than 1 cm between ADUHELM and placebo
- Clinical symptoms were present in 24% of patients treated with ADUHELM 10 mg/kg who had an observation of ARIA (-E and/or -H), compared to 5% of patients on placebo. The most common symptom in patients treated with ADUHELM 10 mg/kg with ARIA was headache (13%). Other frequent symptoms were confusion/delirium/altered mental status/disorientation (5%), dizziness/vertigo (4%), visual disturbance (2%), and nausea (2%). Serious symptoms associated with ARIA were reported in 0.3% of patients treated with ADUHELM 10 mg/kg. Clinical symptoms resolved in the majority of patients (88%) during the period of observation
- Enhanced clinical vigilance for ARIA is recommended during the first 8 doses of treatment with ADUHELM, particularly during titration, as this is the time the majority of ARIA was observed in Studies 1 and 2. If a patient experiences symptoms which could be suggestive of ARIA, clinical evaluation should be performed, including MRI testing if indicated. If ARIA is observed on MRI in the presence of clinical symptoms, careful clinical evaluation should be performed prior to continuing treatment
- Obtain brain MRIs prior to the 7th infusion (first dose of 10 mg/kg) and 12th infusion (sixth dose of 10 mg/kg) of ADUHELM to evaluate for the presence of asymptomatic ARIA. For patients with radiographic findings of ARIA, enhanced clinical vigilance is recommended. Additional MRIs may be considered if clinically indicated. If radiographically severe ARIA-H is observed, treatment may be continued with caution only after a clinical evaluation and a follow-up MRI demonstrates radiographic stabilization (i.e., no increase in size or number of ARIA-H). For ARIA-E or mild/moderate ARIA-H, treatment may continue with caution. If dosing is temporarily suspended, dosing may resume at that same dose and titration schedule. There are no systematic data on continued dosing with ADUHELM following detection of radiographically moderate or severe ARIA. In Studies 1 and 2, temporary dose suspension was required for radiographically moderate or severe ARIA-E and radiographically moderate ARIA-H. In Studies 1 and 2, permanent discontinuation of dosing was required for radiographically severe ARIA-H. The benefits of reaching and maintaining the 10 mg/kg dose should be considered when evaluating a potential dose suspension

E/M Codes for Established Patients

Coding System	Code and Description[13]
CPT®	**99212** - E/M of an established patient, which requires a medically appropriate history and/or examination and straightforward medical decision-making When using time for code selection, 10-19 minutes of total time is spent on the date of the encounter **99213** - E/M of an established patient, which requires a medically appropriate history and/or examination and low level of medical decision-making When using time for code selection, 20-29 minutes of total time is spent on the date of the encounter **99214** - E/M of an established patient, which requires a medically appropriate history and/or examination and moderate level of medical decision-making When using time for code selection, 30-39 minutes of total time is spent on the date of the encounter **99215** - E/M of an established patient, which requires a medically appropriate history and/or examination and high level of medical decision-making When using time for code selection, 40-54 minutes of total time is spent on the date of the encounter

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

Hypersensitivty Reactions

- Angioedema and urticaria were reported in one patient in the placebo-controlled period of Studies 1 and 2, and occurred during the ADUHELM infusion. Promptly discontinue the infusion upon the first observation of any signs or symptoms consistent with a hypersensitivity reaction, and initiate appropriate therapy

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E/M Codes by Site of Care

Site of Care	Medicare[13,15]	Commercial[13]	Medicaid[13]
Physician Practice	CPT® 99202-99205 CPT® 99212-99215	CPT® 99202-99205 CPT® 99212-99215	CPT® 99202-99205 CPT® 99212-99215
Hospital Outpatient Department	G0463	CPT® 99202-99205 CPT® 99212-99215	CPT® 99202-99205 CPT® 99212-99215

Hospital outpatient departments may bundle the service and evaluation with the management for administration of ADUHELM™ (aducanumab-avwa). HCPCS code G0463 is used to indicate a hospital outpatient clinic visit for the assessment and management of a patient.[16]

Hospital Outpatient Billing—Revenue Codes

Relevant Revenue Codes for ADUHELM™ (aducanumab-avwa)

Relevant codes are required for hospital outpatient billing and will vary depending on the revenue center to which your hospital maps ADUHELM. Typically, ADUHELM will be reported using the revenue codes listed below.

Coding System	Code and Description[17]	Location on CMS-1450/ UB-04 Form[8]	Comments
AHA Revenue System	**0250** (Pharmacy general classification)	Field 42† (Loop: 2400; Segment SV201)	Revenue code requirements for claims with a CPT® code for IV infusion may vary.
	0636* (Drug requiring detailed coding)		
	0260 (IV infusion)		
	0510 (Clinic - General Classification)		

AHA=American Hospital Association.

*For Medicare, revenue code 0636 must be used in conjunction with HCPCS code 96413. Private payers may also require revenue code 0636 for ADUHELM.

†The appropriate revenue code should be entered into Field 42 of the CMS-1450/UB-04 claim form.

MRI Code

The following CPT® code is indicated for MRIs[13]

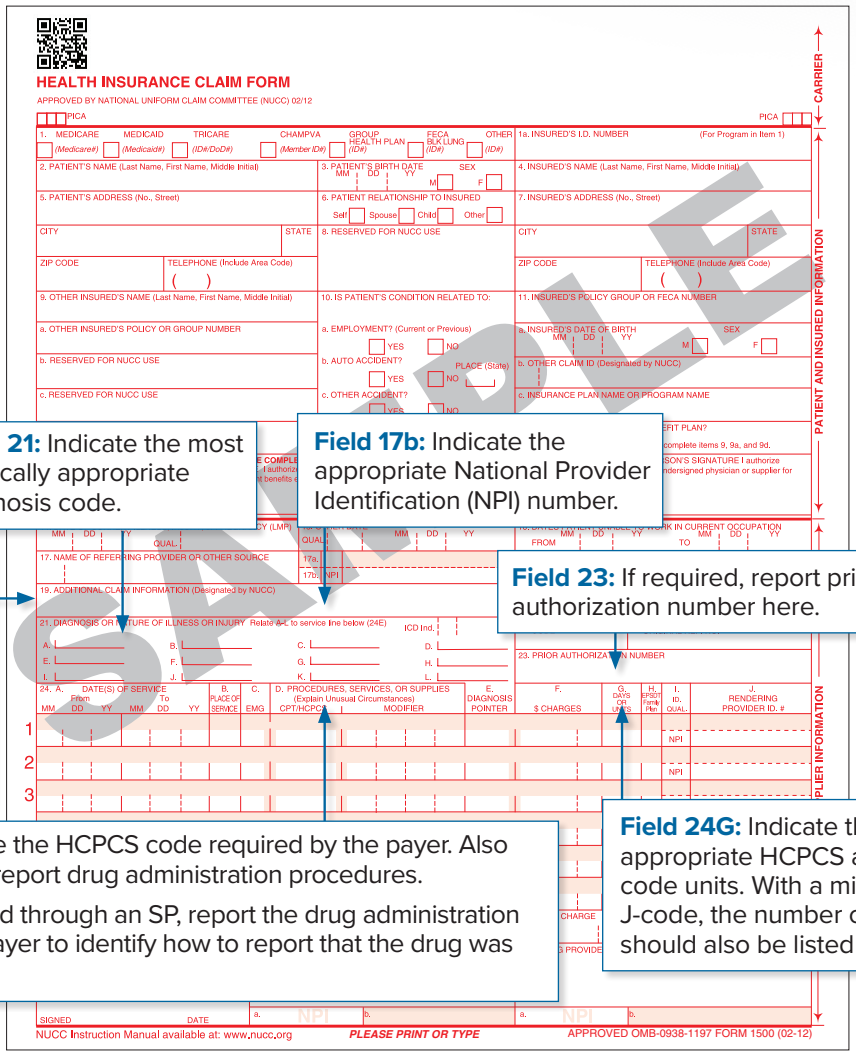
- 70551 (MRI, [brain including brain stem]; without contrast material)

IMPORTANT SAFETY INFORMATION (cont'd)

ADVERSE REACTIONS

- In the combined placebo-controlled and long-term extension periods, 5% (66 out of 1386) of patients in the 10 mg/kg dose group withdrew from the study because of an adverse reaction. The most common adverse reaction resulting in study withdrawal in the combined placebo-controlled and long-term extension periods was ARIA-H superficial siderosis
- The most common adverse reactions reported in at least 2% of patients treated with ADUHELM 10 mg/kg and at least 2% more frequently than in patients on placebo in Studies 1 and 2 were ARIA-E (35% ADUHELM vs. 3% placebo), headache (21% ADUHELM vs. 16% placebo), ARIA-H microhemorrhage (19% ADUHELM vs. 7% placebo), ARIA-H superficial siderosis (15% ADUHELM vs. 2% placebo), fall (15% ADUHELM vs. 12% placebo), diarrhea (9% ADUHELM vs. 7% placebo), and confusion/delirium/altered mental status/disorientation (8% ADUHELM vs. 4% placebo)
- Immunogenicity: The immunogenicity of ADUHELM has been evaluated using an in vitro assay for the detection of binding anti-aducanumab-avwa antibodies. In up to 41 months of treatment in the combined placebo-controlled and long-term extension periods of Studies 1 and 2, up to 0.6% (15/2689) of patients receiving ADUHELM once monthly developed anti-aducanumab-avwa antibodies. Based on the limited number of patients who tested positive for anti-aducanumab-avwa antibodies, no observations were made concerning a potential effect of neutralizing activity of anti-aducanumab-avwa antibodies on exposure or efficacy; however, the available data are too limited to make definitive conclusions regarding an effect on pharmacokinetics, safety, or efficacy of ADUHELM. Quantification of neutralizing anti-aducanumab-avwa antibodies has not been assessed.

Sample CMS-1500 Claim Form—Physician Office Setting



Field 21: Indicate the most medically appropriate diagnosis code.

Field 17b: Indicate the appropriate National Provider Identification (NPI) number.

Field 19: Because ADUHELM has an unspecified J-code, you should include details about product dosing here, such as drug name, NDC number, and number of units.

Field 23: If required, report prior authorization number here.

Field 24D: For ADUHELM, use the HCPCS code required by the payer. Also include appropriate codes to report drug administration procedures.

NOTE: For ADUHELM obtained through an SP, report the drug administration codes here. Check with the payer to identify how to report that the drug was infused if needed.

Field 24G: Indicate the appropriate HCPCS and/or CPT® code units. With a miscellaneous J-code, the number of units should also be listed as 1.

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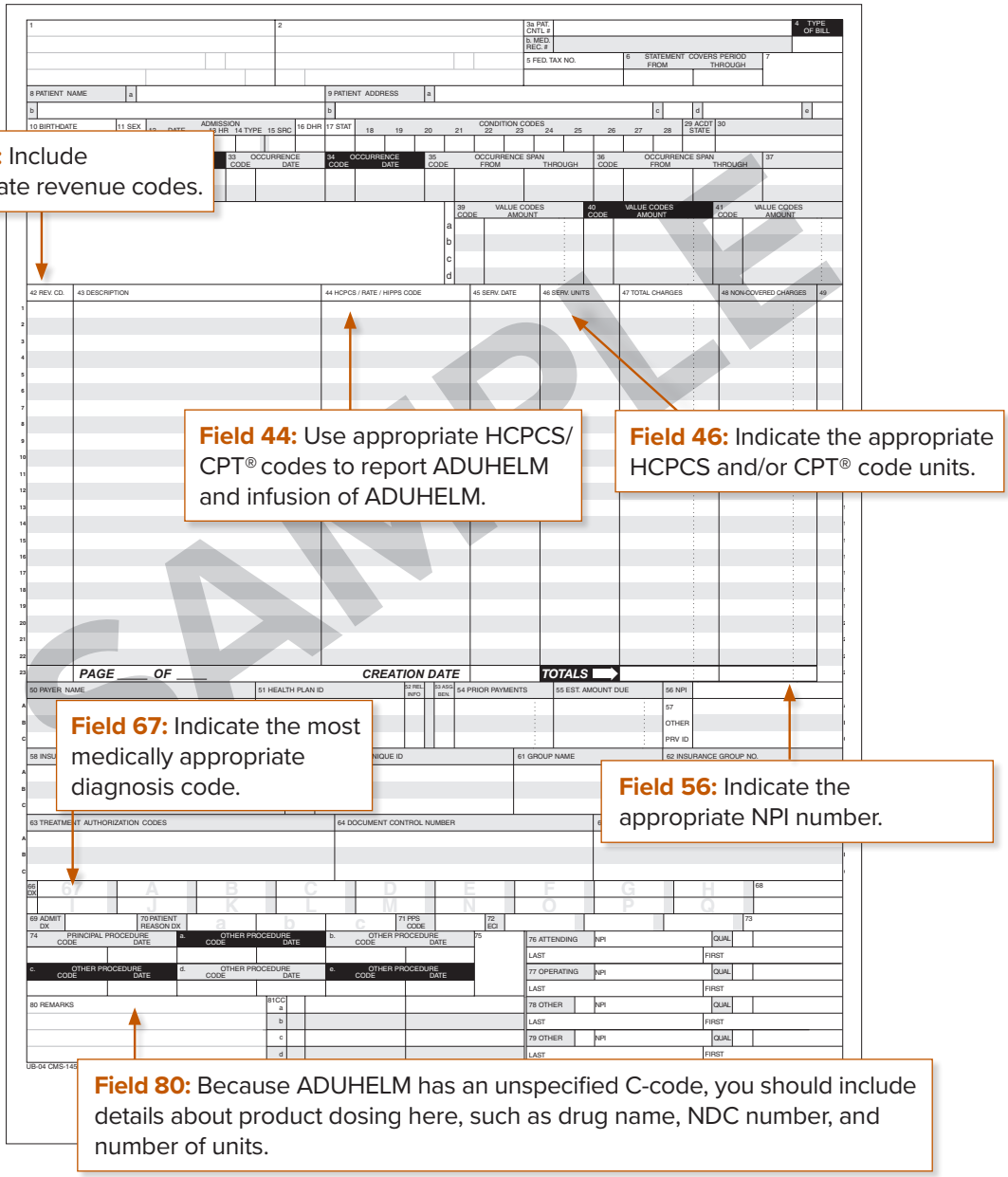
Sample CMS-1450/UB-04 Claim Form—Hospital Outpatient Departments



Please see Important Safety Information throughout and full Prescribing Information.

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