Elucirem™
(gadopiclenol) injection

REIMBURSEMENT SUPPORT

Healthcare providers should code healthcare claims based upon the service that is rendered, the patient's medical record, the coding requirements of each health insurer, and the best coding practices. The accurate completion of reimbursement- or coverage-related documentation is the responsibility of the healthcare provider and patient. Guerbet LLC and its agents make no guarantee regarding reimbursement for any service or item.

Guerbet

REIMBURSEMENT SUPPORT

CODING

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Reimbursement Support can provide guidance on coding and billing for ELUCIREM and related magnetic resonance (MR) procedures.

Assistance is also available for appealing denied or underpaid claims. Available Monday – Friday from 9 AM to 5 PM Eastern Time: 855-368-2736.

Please see Important Safety Information, including Boxed Warning, at the back of the PDF and full Prescribing Information with Medication Guide at https://www.elucirem.com.

REIMBURSEMENT SUPPORT CODING

Procedures and contrast agents must be coded correctly in order to obtain appropriate reimbursement from both Centers for Medicare & Medicaid Services (CMS) and all other third-party payers.

The following describes the types of codes that may be applied when submitting claims for an MR procedure using ELUCIREM:

- **HCPCS** – Healthcare Common Procedure Coding System: Codes used to report the provision of supplies, materials, injections, and certain services and procedures. For example, the HCPCS code for Dotarem is A9575
- **CPT®** – Current Procedural Terminology: Codes used to report the service or procedure that was performed and reported
- **ICD-10-CM** – International Classification of Diseases, Tenth Revision: Codes used to describe signs or symptoms of the patient that would represent a medically necessary reason for performing the procedure
- **NDC** – National Drug Code: A universal product identifier for human drugs in the United States

HCPCS

At this time, there is not a distinct HCPCS code for Elucirem used for contrast-enhanced magnetic resonance imaging (MRI) to detect and visualize lesions with abnormal vascularity in the central nervous system (brain, spine, and associated tissues) and the body (head and neck, thorax, abdomen, pelvis, and musculoskeletal system). Guerbet has applied for a distinct code; in the absence of a product-specific code, a not-otherwise-classified (NOC) HCPCS code is required. When billing an NOC code, payers require additional information: the NDC number, drug name, cost, and units—place information in the electronic equivalent to box 19 on the CMS-1500 claim form or the electronic equivalent to box 80 on the CMS-1450 claim form.

Suggested NOC coding to report ELUCIREM is: J3490 (unclassified drug). Unlike distinct HCPCS codes, NOC drug codes always default to one (1) unit, whereas once a distinct code is issued, the units will be based on the dose administered with each mL being one (1) unit.

CPT Codes

The choice of procedure code to report the procedure should be based on which code most accurately describes the procedure performed and is properly documented in the medical record/procedure report. There are numerous CPT options for MR procedures to detect and visualize lesions with abnormal vascularity in the central nervous system (brain, spine, and associated tissues) and the body (head and neck, thorax, abdomen, pelvis, and musculoskeletal system). Possible options include but are not limited to:

Brain and Neck	
MRI Brain, IACs, or Pituitary w/wo Contrast	70553
MRA Neck w/wo Contrast	70549
MRI Orbits w/wo Contrast	70543
MRI Soft Tissue Neck w/wo Contrast	70543
Abdomen	
MRI Kidneys, Liver, or Pancreas w/wo Contrast	74183
Pelvis	
MRI Bony or ST Pelvis w/wo Contrast	72197
MRI Sacrum/Coccyx w/wo Contrast	72197

Spine	
MRI Cervical Spine w/wo Contrast	72156
MRI Thoracic Spine w/wo Contrast	72157
Extremities	
MRI Lower Extremity w/wo Contrast	73720
MRI Upper Extremity w/wo Contrast	73220
Joints	
MRI Shoulder, Elbow, Wrist, or Clavicle w/wo Contrast	73223
MRI Hip, Knee, or Ankle w/wo Contrast	73723

ICD-10 CM

A covered diagnostic code must be billed with any MR procedure for the procedure and contrast agent to be reimbursed. Covered ICD-10-CM codes will vary by payer; the provider of the service should always verify a patient's individual benefits before scheduling a scan.

IAC: internal auditory canal; MR: Magnetic Resonance; ST: soft tissue.

NDC

There are various NDCs, depending on how ELUCIREM is packaged.

Strength	Sale Unit	NDC
Single-dose Vial (glass)		
1.5 mmol/3 mL	Carton of 10	67684-4230-2
3.75 mmol/7.5 mL	Carton of 10	67684-4231-2
5 mmol/10 mL	Carton of 10	67684-4232-2
Pharmacy Bulk Package (glass)		
25 mmol/50 mL	Carton of 1	67684-4250-3
Single-dose Prefilled Syringe (plastic)		
3.75 mmol/7.5 mL	Carton of 10	67684-4240-2
5 mmol/10 mL	Carton of 10	67684-4241-2

Hospital Revenue Codes for Chargemaster – Hospital Outpatient Department

Revenue	Descriptor
0320	Radiology diagnostic
0636	Drugs that require detail coding

Most third-party payers require some type of prior authorization for advanced imaging, and it may be necessary to provide the following information when making a prior authorization request:

- Patient demographics, including name, insurance policy and group numbers, and date of birth
- Physician information, including name and National Provider Identifier (NPI) number
- Facility information, including name and tax ID number
- Setting of care
  - Independent diagnostic testing facility (IDTF)
  - Hospital inpatient
  - Hospital outpatient
- Date of service
- Patient diagnosis and relevant ICD-10 code(s)
- Patient clinical notes detailing the relevant diagnosis
- Relevant CPT and HCPCS codes for services/products to be performed or provided
- NDC for contrast agent

REIMBURSEMENT SUPPORT BEST PRACTICES

When using ELUCIREM, follow these steps for successful billing:

- Get to know how the MR scans where ELUCIREM will be used are covered by the major payers in your area
- Contact ELUCIREM Reimbursement Support for assistance, as they have a database of coverage policies for third-party payers
- Review your contracts with the payers to see how they will cover ELUCIREM or if you need to amend your contracts for ELUCIREM
- Perform a benefit investigation before scheduling any scan
    - Confirm coverage, co-pay, if there is a deductible, and if prior authorization is required
- Where prior authorization is required:
    - Determine if the imaging facility you wish to refer your patient to is in-network for the payer
    - Can you do the prior authorization online or is there a specific form to use?
    - Is there a radiology benefit manager (RBM) to work with?
    - Can you do that request online or do you need a specific form/worksheet?

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IMPORTANT SAFETY INFORMATION

WARNING: NEPHROGENIC SYSTEMIC FIBROSIS (NSF)
See full prescribing information for complete boxed warning

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.

- **The risk for NSF appears highest among patients with:**
  - **Chronic, severe kidney disease (GFR <30 mL/min/1.73 m^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.**

Indications and Usage

ELUCIREM™ (gadopiclenol) injection is indicated in adult and pediatric patients aged 2 years and older for use with magnetic resonance imaging (MRI) to detect and visualize lesions with abnormal vascularity in the central nervous system (brain, spine, and associated tissues), and the body (head and neck, thorax, abdomen, pelvis, and musculoskeletal system).

Contraindications

History of hypersensitivity reactions to ELUCIREM

Warnings and Precautions

- **Nephrogenic Systemic Fibrosis:** GBCAs increase the risk for NSF among patients with impaired elimination of the drugs. Avoid use of GBCAs among these patients unless the diagnostic information is essential and not available with non-contrast MRI or other modalities. The GBCA-associated NSF risk appears highest for patients with chronic, severe kidney disease as well as patients with acute kidney injury.

- **Hypersensitivity Reactions:** With GBCAs, serious hypersensitivity reactions have occurred. In most cases, initial symptoms occurred within minutes of GBCA administration and resolved with prompt emergency treatment. Before ELUCIREM 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 ELUCIREM.

- **Gadolinium Retention:** Gadolinium is retained for months or years in several organs. Linear GBCAs cause more retention than macrocyclic GBCAs. Consequences of gadolinium retention in the brain have not been established. Pathologic and clinical consequences of GBCA administration and retention in skin and other organs have been established in patients with impaired renal function. While clinical consequences of gadolinium retention have not been established in patients with normal renal function, certain patients might be at higher risk. These include patients requiring multiple lifetime doses, pregnant and pediatric patients, and patients with inflammatory conditions. Consider the retention characteristics of the agent when choosing a GBCA for these patients. Minimize repetitive GBCA imaging studies, particularly closely spaced studies when possible.

IMPORTANT SAFETY INFORMATION (CONT'D)

- **Acute Kidney Injury:** In patients with chronically reduced renal function, acute kidney injury requiring dialysis has occurred with the use of GBCAs. The risk of acute kidney injury may increase with increasing dose of the contrast agent. Do not exceed the recommended dose.
- **Extravasation and Injection Site Reactions:** Injection site reactions such as injection site pain have been reported in the clinical studies with ELUCIREM. Extravasation during ELUCIREM administration may result in tissue irritation. Ensure catheter and venous patency before the injection of ELUCIREM.
- **Interference with Visualization of Lesions Visible with Non-Contrast MRI:** As with any GBCA, ELUCIREM may impair the visualization of lesions seen on non-contrast MRI. Therefore, caution should be exercised when Gadopiclenol MRI scans are interpreted without a companion non-contrast MRI scan.

Adverse Reactions:

In clinical trials, the most frequent adverse reactions that occurred in > 0.2% of patients who received ELUCIREM included: injection site pain, headache, nausea, injection site warmth, injection site coldness, dizziness, and localized swelling.

Adverse reactions that occurred with a frequency ⩽ 0.2% in patients who received 0.05 mmol/kg BW ELUCIREM included: maculopapular rash, vomiting, worsened renal impairment, feeling hot, pyrexia, oral paresthesia, dysgeusia, diarrhea, pruritus, allergic dermatitis, erythema, injection site paresthesia, Cystatin C increase, and blood creatinine increase.

Use in Specific Populations

- **Pregnancy:** GBCAs cross the human placenta and result in fetal exposure and gadolinium retention. There are no available data on ELUCIREM use in pregnant women to evaluate for a drug-associated risk of major birth defects, miscarriage or other adverse maternal or fetal outcomes.
- **Lactation:** There are no data on the presence of ELUCIREM in human milk, the effects on the breastfed infant, or the effects on milk production. However, published lactation data on other GBCAs indicate that 0.01 to 0.04% of the maternal gadolinium dose is excreted in breast milk.
- **Pediatric Use:** The safety and effectiveness of ELUCIREM have not been established in pediatric patients younger than 2 years of age.
- **Geriatric Use:** This drug is known to be substantially excreted by the kidney, and the risk of adverse reactions to this drug may be greater in patients with impaired renal function.
- **Renal Impairment:** In patients with renal impairment, the exposure of gadopiclenol is increased compared to patients with normal renal function. This may increase the risk of adverse reactions such as nephrogenic systemic fibrosis (NSF). Avoid use of GBCAs among these patients unless the diagnostic information is essential and not available with non-contrast MRI or other modalities. No dose adjustment of ELUCIREM is recommended for patients with renal impairment. ELUCIREM can be removed from the body by hemodialysis.

You are encouraged to report negative side effects of prescription drugs to the FDA.
Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

Please see **full Prescribing Information**, including **Boxed Warning** and patient **Medication Guide**, for additional Important Safety Information. **https://www.elucirem.com/**