Cohere Medicare Advantage Policy - Computed Tomography (CT), Orbit/Ear/Sella

Clinical Guidelines for Medical Necessity Review

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Important Notices

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Guideline Information:

Specialty Area: Diagnostic Imaging
Guideline Name: Computed Tomography (CT), Orbit/Ear/Sella

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Type: [**X**] Adult (18+ yo) | [**X**] Pediatric (0-17yo)

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Medical Necessity Criteria

Service: Computed Tomography (CT), Orbit/Ear/Sella

Benefit Category

Not applicable.

Please Note: This may not be an exhaustive list of all applicable Medicare benefit categories for this item or service.[1-5]

Related CMS Documents

Please refer to CMS Medicare Coverage Database for the most current applicable CMS National Coverage.[1-5]

- National Coverage Determination (NCD). Computed Tomography (220.1)
- Local Coverage Determination (LCD). MRI and CT Scans of the Head and Neck (L37373)
- Billing and Coding: MRI and CT Scans of the Head and Neck (A57204)
- Local Coverage Determination (LCD). MRI and CT Scans of the Head and Neck (L35175)
- Billing and Coding: MRI and CT Scans of the Head and Neck (A57215)

Recommended Clinical Approach

Computed tomography (CT) is often the first-line imaging exam for many disorders of the extracranial head due to its speed, availability, and high resolution. In the setting of trauma and other primary osseous abnormalities, contrast is not routinely employed. For many soft-tissue processes, contrast is preferred. The specific area imaged, reformations performed, and radiation dose depends upon the clinical question being addressed and is deferred to the supervising radiologist.[6]

Evaluation of Clinical Harms and Benefits

Cohere Health uses the criteria below to ensure consistency in reviewing the conditions to be met for coverage of Computed Tomography (CT), Orbit/Ear/Sella. This process helps to prevent both incorrect denials and inappropriate approvals of medically necessary services. Specifically, limiting incorrect approvals reduces the risks associated with unnecessary procedures, such as complications from surgery, infections, and prolonged recovery times.

The potential clinical harms of using these criteria may include:

- Inherent risk of procedure: There are inherent risks of imaging, including cumulative radiation exposure, contrast, allergy, nephrotoxicity, and contrast extravasation into surrounding tissues.[7-10]
- Potential danger to pregnancy: CT imaging completed during pregnancy confers a dose of ionizing radiation to the fetus and is generally only utilized when the potential benefits of this specific imaging modality outweigh the risks to the pregnancy.[11] Fetal risk includes fetal demise, intrauterine growth restriction, microcephaly, delayed intellectual development, risk of childhood cancer, and fetal thyroid injury.[11]
- Increased healthcare costs and complications from the inappropriate use of additional interventions.[12]

The clinical benefits of using these criteria include:

- Weighted average head and neck images acquired using dual-energy CT (DECT) demonstrate superior objective and subjective image quality compared to single-energy computed tomography (SECT) performed with tube voltage adaptation (TVA).[13]
- CT radiation doses vary across imaging facilities and are often higher than needed. However, detailed feedback on CT radiation dose combined with actionable suggestions and quality improvement education significantly reduces radiation doses, particularly organ doses.[14]
- A CT assessment tool developed to assess soft tissue damage secondary to tumor, surgery, or radiation, in patients with lymphedema

and fibrosis (LEF) following treatment for head and neck cancer provides a standardized method for assessing critical sites affected by LEF.[15]
- Cone-beam CT with a large field of view can accurately identify craniofacial anomalies and quantify asymmetries between the nonaffected and affected sides of the face in Goldenhar syndrome, a rare disease with hemifacial microsomia and craniofacial disorders including auricular anomalies, for an efficient maxillofacial treatment planning.[16]
- Enhanced overall patient satisfaction and healthcare experience.

This policy includes provisions for expedited reviews and flexibility in urgent cases to mitigate risks of delayed access. Evidence-based criteria are employed to prevent inappropriate denials, ensuring that patients receive medically necessary care. The criteria aim to balance the need for effective treatment with the minimization of potential harms, providing numerous clinical benefits in helping avoid unnecessary complications from inappropriate care.

In addition, the use of these criteria is likely to decrease inappropriate denials by creating a consistent set of review criteria, thereby supporting optimal patient outcomes and efficient healthcare utilization.

Medical Necessity Criteria

Indications

➔ **Computed tomography (CT), orbit/ear/fossa** is considered appropriate if **ANY** of the following is **TRUE**[6]:
- ◆ Orbital indications, including **ANY** of the following:
  - Trauma-related conditions, including traumatic visual defect with suspected orbital injury[17]; **OR**
  - **ANY** of the following if MRI is contraindicated or cannot be performed:
    - Congenital conditions (e.g., capillary hemangioma, optic nerve hypoplasia); **OR**
    - Optic neuritis; **OR**
    - Eye pain, with history or other sign or symptom, indicating non-ischemic pathology; **OR**
    - Ophthalmoplegia; **OR**

    - Eye movement abnormality in a child (e.g., strabismus, nystagmus in a child 6 months or older); **OR**
    - Vision loss or visual field deficit with history or other signs or symptoms indicating non-ischemic intra-orbital pathology; **OR**
- Conditions, known or suspected, including **ANY** of the following[17]:
    - Initial staging, treatment response, surveillance, complication, recurrence, treatment planning, or of an orbital mass (e.g., dermoid, melanoma, lymphoma, metastases)[18]; **OR**
    - Orbital pseudotumor or orbital inflammatory disease; **OR**
    - Osseous lesions (e.g., fibrodysplasia, Paget's); **OR**
    - Foreign-body, suspected clinically or seen on prior imaging; **OR**
    - Orbital infectious process, suspected or known, that has failed medical management (e.g., orbital cellulitis not responding appropriately to antibiotics) or patient is pediatric or immunocompromised; **OR**
    - Scleritis confirmed clinically with failure of medical management or with complication suspected[19]; **OR**
    - Uveitis, confirmed clinically with complication suspected; **OR**
    - Thyroid orbitopathy; **OR**
    - Venous conditions (e.g., orbital varices); **OR**
- Additional evaluation is needed when etiology remains unclear following a complete eye examination that includes funduscopy, including **ANY** of the following:
    - Diplopia; **OR**
    - Enophthalmos[20]; **OR**
    - Exophthalmos; **OR**
    - Orbital asymmetry; **OR**
    - Preseptal or post-septal orbital mass, otherwise unexplained; **OR**
    - Proptosis; **OR**
    - Unilateral papilledema; **OR**

        - Orbital hemorrhage; **OR**
    - Preoperative, postoperative, or pre-treatment evaluation for surgery, radiation, or chemotherapy; **OR**
- Temporal bone and inner ear indications including **ANY** of the following:
    - Conditions, known or suspected, including **ANY** of the following[21]; **OR**
        - Aberrant and symptomatic congenital or acquired anatomy (e.g., stenosis of the external auditory canal [EAC] or dehiscence of the superior semicircular canal, facial nerve canal, carotid canal, or jugular bulb); **OR**
        - Cholesteatoma, initial and 9 to 12-month postoperative follow-up; **OR**
        - Tympanosclerosis; **OR**
        - Neoplastic conditions, detection, and follow-up (including tumors of the internal or external auditory canal, inner ear, and mastoid); **OR**
        - Otitis media, recurrent with at least 3 episodes in the past 12 months, with complications suspected (e.g., hearing loss, intracranial extension, mastoiditis)[22]; **OR**
        - Malignant otitis externa, unresponsive to antibiotics; **OR**
        - Mastoiditis; **OR**
        - Other infectious processes involving the middle or inner ear, where imaging is needed to direct appropriate management; **OR**
        - Bell's palsy or other facial nerve abnormalities requiring evaluation of the extracranial portion of the nerve (when MRI is contraindicated or cannot be performed); **OR**
        - Tinnitus, unexplained by history or physical examination, and is worsening or affects daily function (when MRI is contraindicated or cannot be performed)[23]; **OR**
    - Symptoms or signs evaluated by complete auditory examination, including **ANY** of the following[21]:

        - Conductive, mixed-conductive, or congenital hearing loss; **OR**
        - Sensorineural hearing loss, acquired or congenital, (when MRI is contraindicated or cannot be performed); **OR**
        - Total deafness, otherwise unexplained; **OR**
        - Vertigo, unexplained by history or physical examination with **ANY** of the following:
            - Worsening; **OR**
            - Affects daily function; **OR**
            - Associated hearing loss or other neurological deficits; **OR**
            - History of prior infection (e.g., otitis or meningitis); **OR**
            - History of prior trauma; **OR**
    - Trauma-related conditions related to the ear, including evaluation of cerebrospinal fluid leak[23-25]; **OR**
    - Preoperative, postoperative, or pre-treatment evaluation for surgery, radiation, or chemotherapy (including evaluation for cochlear implant); **OR**
    - Vascular conditions, known or suspected, related to the ear or temporal bone, including evaluation of pulsatile tinnitus[26]; **OR**
- Sellar and posterior fossa indications, including **ANY** of the following indications related to a sella or posterior fossa:
    - Sellar mass (including pituitary masses) is suspected due to documented clinical or laboratory findings (e.g., prolactinemia); **OR**
    - Visual field deficit (e.g., bitemporal hemianopsia) indicating optic nerve compression; **OR**
    - Other neoplastic conditions, known, suspected, or suggested by prior imaging (e.g., meningioma); **OR**
    - Trauma-related conditions; **OR**
    - Pituitary dysfunction, suggested by documented laboratory or clinical abnormalities (e.g., pituitary failure due to conditions such as pituitary apoplexy); **OR**
    - Vascular conditions, known or suspected, including aberrant anatomy; **OR**

- Preoperative, postoperative, or pre-treatment evaluation for surgery, radiation, or chemotherapy (including pre-operative planning for removal of the pituitary tumor); **OR**

◆ Repeat imaging (defined as repeat request following recent imaging of the same anatomic region with the same modality), in the absence of established guidelines, will be considered reasonable and necessary if **ANY** of the following is **TRUE**:

- New or worsening symptoms, such that repeat imaging would influence treatment; **OR**
- One-time clarifying follow-up of a prior indeterminate finding; **OR**
- In the absence of change in symptoms, there is an established need for monitoring which would influence management.

Non-Indications

➔ **Computed tomography (CT), orbit/ear/fossa** is not considered appropriate if **ANY** of the following is **TRUE**[27]:

◆ If contrast is used, history of anaphylactic allergic reaction to iodinated contrast media.

*NOTE: The referring professional and radiologist should discuss the risks and benefits of contrast media administration, including possible prophylaxis, in patients with chronic or worsening kidney disease or severe renal failure.
**NOTE: CT in pregnant patients should be requested at the discretion of the ordering provider and obstetric care provider.
***NOTE: CT in patients with claustrophobia should be requested at the discretion of the ordering provider.

Disclaimer on Radiation Exposure in Pediatric Population

Due to the heightened sensitivity of pediatric patients to ionizing radiation, minimizing exposure is paramount. At Cohere, we are dedicated to ensuring that every patient, including the pediatric population, has access to appropriate imaging following accepted guidelines. Radiation risk is dependent mainly on the patient's age at exposure, the organs exposed, and the patient's sex, though there are other variables. The following technical guidelines are provided to ensure safe and effective imaging practices:

Radiation Dose Optimization: Adhere to the lowest effective dose principle for pediatric imaging. Ensure that imaging protocols are specifically tailored for pediatric patients to limit radiation exposure.[28-29]

Alternative Modalities: Prioritize non-ionizing imaging options such as ultrasound or MRI when clinically feasible, as they are less likely to expose the patient to ionizing radiation. For instance, MRI or ultrasound should be considered if they are more likely to provide an accurate diagnosis than CT, fluoroscopy, or radiography.[28-29]

Cumulative Dose Monitoring: Implement systems to track cumulative radiation exposure in pediatric patients, particularly for those requiring multiple imaging studies. Regularly reassess the necessity of repeat imaging based on clinical evaluation.[28-29]

CT Imaging Considerations: When CT is deemed the best method for achieving a correct diagnosis, use the lowest possible radiation dose that still yields reliable diagnostic images.[28-29]

Cohere Imaging Gently Guideline

The purpose of this guideline is to act as a potential override when clinically indicated to adhere to Imaging Gently and Imaging Wisely guidelines and As Low As Reasonably Possible (ALARA) principles.

Level of Care Criteria

Inpatient or Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
70480	Computed tomography (CT), orbit, sella, or posterior fossa or outer, middle, or inner ear; without contrast material
70481	Computed tomography (CT), orbit, sella, or posterior fossa; with contrast material(s)
70482	Computed tomography (CT), orbit, sella, or posterior fossa; without contrast material, followed by contrast material(s) and further sections

76380	Computed tomography, limited or localized follow-up study

Disclaimer: G, S, I, and N Codes are non-covered per CMS guidelines due to their experimental or investigational nature.

Medical Evidence

Bedernik et al. (2022) conducted a randomized control trial (RCT) to assess image quality by comparing single-energy computed tomography (SECT) with automated tube voltage adaptation (TVA) to dual-energy CT (DECT) weighted average images. A total of 80 patients underwent SECT or radiation dose-matched DECT. The effective radiation dose (ED) showed no significant difference between the SECT and DECT study groups. Compared to the SECT group, the DECT group exhibited significantly higher contrast-to-noise ratio differences (CNRD) for jugular veins relative to fatty tissue and muscle tissue relative to fatty tissue. However, the CNRD for jugular veins relative to muscle tissue was comparable between groups. Image artifacts were also less pronounced, and overall diagnostic acceptability was higher in the DECT group. Overall, DECT-weighted average images demonstrate superior objective and subjective image quality compared to SECT performed with TVA in head and neck imaging.[13]

Smith-Bindman et al. (2020) performed an RCT to study the efficacy of interventions to lower the amount of radiation exposure. The RCT included 864,080 adults at 100 facilities who underwent a CT scan, including head CT scans (n = 1,156,657 scans). The study included two primary measures: the percentage of high-dose CT scans and the average effective dose administered at the facility level. The study's secondary measure included the doses received by specific organs - outcomes assessed for the impact of the interventions and outcomes post-intervention. Data were contrasted with pre-intervention data, utilizing hierarchical generalized linear models that accounted for temporal patterns and patient attributes. In conclusion, data regarding CT radiation dosage and practical recommendations may improve quality, including significant dose reductions, especially for organ-specific doses.[14]

Aulino et al. (2018) reported on a clinical trial that focused on an assessment tool for the late effect continuum of lymphedema and fibrosis (LEF) for patients with head and neck cancer (HNC) undergoing CT. The tool evaluates areas of soft tissue damage resulting from tumors, surgical interventions, or radiation therapy. The tool analyzed CT scans taken before and after treatment in 10 patients with HNC. The finalized tool has 11 elements, including assessing fat stranding at six specific sites, measuring epiglottic thickness, and measuring prevertebral soft tissue thickness at C3. The trial includes 176 CT scans from 20 patients (with a range of 4-14 scans per patient). The final version of the LEF assessment tool (CT-LEFAT) offers a standardized approach to assess critical sites affected by soft tissue damage. Studies continue to evaluate reliability and validity.[15]

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