Chapter 13 Section 1.1

Provisional Coverage For Emerging Services And Supplies

Issue Date: December 1, 2015
Authority: 10 USC Chapter 55, Section 1079c

1.0 BACKGROUND

Section 704 of the National Defense Authorization Act for Fiscal Year 2015 (NDAA FY 2015) provided discretionary authority for provisional TRICARE coverage for emerging healthcare services and supplies.

2.0 POLICY

2.1 Consideration Of Evidence

In making a provisional coverage determination, the Assistant Secretary of Defense for Health Affairs (ASD(HA)) may consider—

- Clinical trials published in refereed medical literature;
- Formal technology assessments;
- The positions of national medical policy organizations;
- National professional associations;
- National expert opinion organizations; and
- Such other validated evidence as the Secretary considers appropriate.

2.2 Independent Evaluation

In making a provisional coverage determination the ASD(HA) may also arrange for an evaluation from the Institute of Medicine of the National Academies of Sciences or such other independent entity as the ASD(HA) selects.

2.3 Duration And Terms Of Coverage

2.3.1 Provisional coverage of a service or supply is effective for up to five years, but may be terminated at any time prior to the five year expiration date. Specific effective dates and expiration dates for each episode of provisional coverage will be specified in Figure 13.1.1-1 of this policy.

2.3.2 Prior to the expiration of provisional coverage of a service or supply, the ASD(HA) shall determine the coverage, if any, that will follow such provisional coverage and take appropriate action to implement such a determination. If the ASD(HA) determines that the implementation of such determination regarding coverage requires legislative action, the ASD(HA) shall make a timely recommendation to Congress regarding such legislative action.

2.3.3 The ASD(HA), at any time, may:

2.3.3.1 Terminate the provisional coverage of a service or a supply prior to the five year expiration date referenced in paragraph 2.3.1.

2.3.3.2 Establish or disestablish terms and conditions for such coverage.

2.3.3.3 Take any action with respect to such coverage.

2.4 Public Notice

The ASD(HA) shall promptly publish, on a publicly accessible Internet website of the TRICARE program, a notice for each service or supply that receives provisional coverage, including any terms and conditions for such coverage. Go to http://www.tricare.mil/provisionalcoverage.

2.5 Finality of Determinations

Any determination by the ASD(HA) to approve or disapprove a specific service or supply under the provisional coverage policy shall be final.

3.0 APPLICABILITY

Approved provisional coverage of services and supplies applies to all TRICARE-eligible beneficiaries.

4.0 CONTRACTOR RESPONSIBILITIES

The contractor shall:

4.1 Preauthorize the approved provisional coverage if required and verify coverage criteria are met according to all indications detailed in Figure 13.1.1-1. Only the covered criteria/indications listed in Figure 13.1.1-1, "Coverage Guidelines" may be considered when authorizing care. See the TRICARE Operations Manual (TOM), Chapter 7, Section 2.

4.2 Issue an authorization to the provider and beneficiary once a determination is made, if preauthorization is required. The authorization shall include a list of all authorized services. The authorization must also include the following information: "[INSERT THE PRIMARY PROCEDURE/ DEVICE/TREATMENT CODES] for the treatment of [INSERT PRIMARY DIAGNOSIS CODE] is an emerging service or supply."

4.2.1 Prime travel benefits shall be authorized in accordance with TRICARE Reimbursement Manual (TRM), Chapter 1, Section 30.

4.2.2 Issue a denial to the provider and the beneficiary if coverage criteria requirements are not met.

4.3 Ensure all TRICARE Encounter Data (TED) requirements outlined in the TRICARE Systems Manual (TSM), Chapter 2, Section 2.8 are met including appropriate use of a Special Processing Code to identify provisional coverage records. A unique Special Processing Code will be created for

each new Provisional Coverage medical benefit. See the applicable medical benefit description and Special Processing Code in Figure 13.1.1-1.

4.4 Manage and resolve all inquiries related to the approved coverage.

4.5 Authorize benefits for otherwise covered treatment of complications resulting from a surgery or treatment authorized under this Provisional Coverage policy even if the provisional coverage status of such treatment is later terminated.

4.6 If preauthorization of care that otherwise meets the requirement of this policy is not obtained, the provision of the TRM, Chapter 1, Section 28 applies. Contractors shall apply the reduction in payment outlined in that section.

FIGURE 13.1.1-1 APPROVED PROVISIONAL COVERAGE FOR EMERGING SERVICES AND SUPPLIES

Treatment & Diagnosis:	Digital Breast Tomosynthesis (DBT) for Breast Cancer Screening
Effective Date:	January 1, 2020.
Termination Date:	December 31, 2024.
Preauthorization:	Not required.
Coverage Guidelines:	Digital Breast Tomosynthesis (DBT), also known as three-dimensional mammography, for breast cancer screening Current Procedural Terminology (CPT)[1] procedure codes 77063 and 770 67) may be covered annually instead of the conventional two-dimensional screening mammography. For all women beginning at age 40. Covered annually beginning at age 30 for women who have a 15% or greater lifetime risk of breast cancer (according to risk assessment tools based on family history such as the Gail model, the Claus model, and the Tyrer-Cuzick model), or who have any of the following risk factors: • History of breast cancer, Ductal Carcinoma In Situ (DCIS), Lobular Carcinoma In Situ (LCIS), Atypical Ductal Hyperplasia (ADH), or Atypical Lobular Hyperplasia (ALH); • Extremely dense breasts when viewed by mammogram; • Known BRCA1 or BRCA2 gene mutation; • First-degree relative (parent, child, sibling) with a BRCA1 or BRCA2 gene mutation, and have not had genetic testing themselves; • Radiation therapy to the chest between the ages of 10 and 30 years; or • History of Li-Fraumeni, Cowden, or Bannayan-Riley-Ruvalcaba syndrome, or a first-degree relative with a history of one of these syndromes. The contractor shall cover DBT under the provisional coverage policy as a primary preventive breast cancer screening otherwise covered under 32 CFR 199.4(e)(28). Thus, the contractor shall not charge copayments or cost-shares associated with this service. The contractor shall not charge TRICARE Select enrollees a cost-share when the enrollee receives this service from network or non-network providers. The contractor shall not require TRICARE Prime enrollees to have a referral or authorization when the enrollee receives this service from any network provider within their region of enrollment. If a TRICARE Prime clinical preventive service is not available from a network provider (e.g., a network provider is not available within prescribed access parameters), the contractor shall allow an enrollee to receive the service from a non-network provider with a referral from the Primary Care Manager (PCM). If a TRICARE Prime enrollee uses a non-network provider without first obtaining a referral from the PCM, the contractor shall apply the Point of Service (POS) option for payment. TED Special Processing Code: DB [1] CPT only © 2006 American Medical Association (or such other date of publication of CPT). All Rights Reserved.

FIGURE 13.1.1-1 APPROVED PROVISIONAL COVERAGE FOR EMERGING SERVICES AND SUPPLIES (CONTINUED)

Treatment & Diagnosis:	Platelet Rich Plasma Injections for the treatment of Musculoskeletal Conditions
Effective Date:	October 1, 2019.
Termination Date:	September 30, 2024.
Preauthorization:	Not required.

Coverage Guidelines:	Platelet Rich Plasma (PRP) injections (CPT[2] 0232T) is covered when the following criteria are met:
	• Patient is diagnosed with mild to moderate chronic osteoarthritis of the knee; AND
	  • Conservative treatment such as physical therapy, diet and exercise, has been unsuccessful after three months or is contraindicated; AND
	  • Radiographic evidence of osteoarthritis.
	OR
	• Patient is diagnosed with lateral epicondylitis; AND
	  • Evidence of diagnosis on physical exam.
	  • Radiographic exam not required.
	  • Conservative treatment such as physical and occupational therapy has been unsuccessful after three months or is contraindicated.
	TED Special Processing Code: MC
	Note: PRP shall be prepared and stored in accordance with U.S. Food and Drug Administration (FDA) regulation titled "Additional Standards for Human Blood and Blood Products" found in 21 CFR, Section 640.34(D) Processing.

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FIGURE 13.1.1-1 APPROVED PROVISIONAL COVERAGE FOR EMERGING SERVICES AND SUPPLIES (CONTINUED)

Treatment & Diagnosis:	Open, Arthroscopic and Combined Hip; Surgical for the treatment of Femoroacetabular Impingement (FAI)
Effective Date:	January 1, 2016.
Termination Date:	December 31, 2018.
Preauthorization:	Required.

Coverage Guidelines:	Open, arthroscopic and combined hip surgery is covered when the following criteria are met:
	• Moderate to severe and persistent activity limiting hip pain that is worsened by flexion activities.
	• Physical examination consistent with the diagnosis of FAI with at least one positive test required:
	  • Positive impingement sign (pain when bringing the knee up towards the chest and then rotating it inward towards the opposite shoulder); or
	  • Flexion Abduction External Rotation (FABER) provocation test (the test is positive if it elicits similar pain as complained by the patient or the range of motion of the hip is significantly decreased compared to the contralateral hip); or
	  • Posterior inferior impingement test (the test is positive if it elicits similar pain as complained by the patient).
	• Failure to improve with greater than three months of conservative treatment (e.g., physical therapy, activity modification, non-steroidal anti-inflammatory medications, intra-articular injection, etc.). Requests shall include what conservative treatments were used and how long; and
	• Radiographic evidence of FAI:
	  • CAM:
	  1. Pistol-grip deformity (characterized on radiographs by flattening of the usually concave surface of the lateral aspect of the femoral head due to an abnormal extension of the more horizontally oriented femoral epiphysis); or
	  2. Alpha angle greater than 50 degrees (measurement of an abnormal alpha angle from an oblique axial image along the femoral neck); or
	  • Pincer:
	  1. Coxa profunda (floor of the fossa acetabuli touching or overlapping the ilioischial line medially); or
	  2. Acetabular retroversion (the alignment of the mouth of the acetabulum does not face the normal anterolateral direction, but inclines more posterolaterally); or
	  3. Os acetabuli (an ossicle located at the acetabular rim); or
	  4. Protrusio acetabuli (an anteroposterior radiograph of the pelvis that demonstrates a center-edge angle greater than 40 degrees and medicalization of the medial wall of the acetabulum past the ilioischial line); and
	• Absence of advanced arthritis (i.e., Tönnis Grade 2 [small cysts, moderate joint space narrowing, moderate loss of head sphericity] or Tönnis Grade 3 [large cysts, severe joint space narrowing, severe deformity of the head]).
	• Inclusion criteria must be documented.

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