



To: DualChoice IPAs & PCPs
From: IEHP – Provider Relations
Date: September 8, 2021
Subject: **CMS ALERT: Human Cell and Tissue Products**

Inland Empire Health Plan (IEHP) would like to share the following message from Centers for Medicare and Medicaid Services (CMS) concerning proper use of Human Cell and Tissue Products.

Below is a summary of the enclosed CMS Alert:

- CMS has noted an uptick in questionable billing for services related to amniotic tissue injections using human cell and tissue products.
- Per the FDA, amniotic tissue products may not be used for the treatment of any orthopedic conditions, including osteoarthritis, tendonitis, disc disease, tennis elbow, back pain, hip pain, knee pain, neck pain, or shoulder pain.
- Medicare provides coverage of amniotic tissue products for wound healing, nothing else.

Please review the enclosed HPMS Memo for further details, including a list of commonly used Q Codes and CPT codes indicative of inappropriate use of human cell and tissue products.

As a reminder, all communications sent by IEHP can also be found on our Provider portal at:
www.iehp.org > Providers > Plan Updates > Correspondence

If you have any questions, please do not hesitate to contact the IEHP Provider Relations Team at (909) 890-2054 or (866) 223-4347.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

7500 Security Boulevard, Mailstop AR-21-55

Baltimore, Maryland 21244-1850



Investigations & Fraud Prevention Partnership Group

Date: August 10, 2021

To: All Medicare Advantage Organizations (MAOs) and Prescription Drug Plan Sponsors (PDPs)

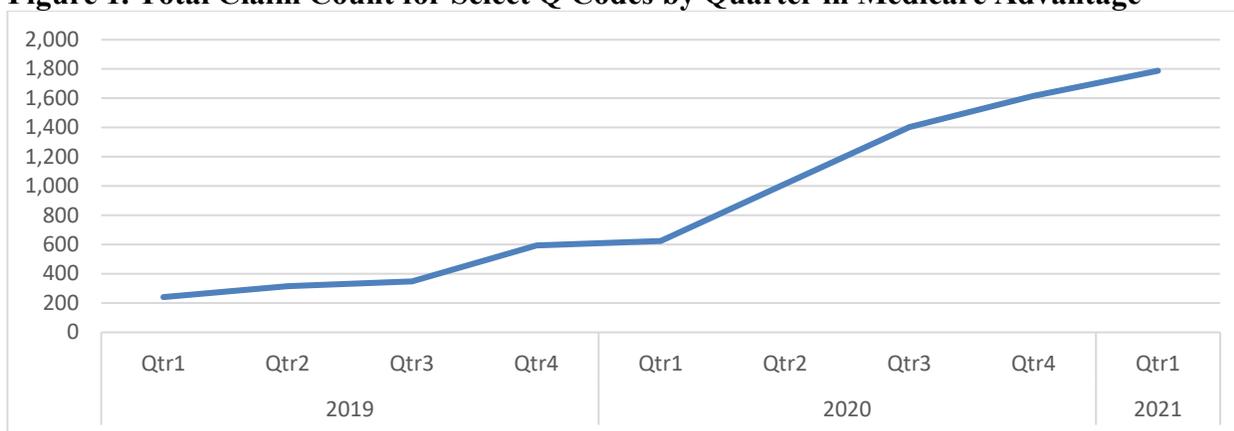
From: Sherri McQueen, Group Director
Investigations and Fraud Prevention Partnerships Group, Center for Program Integrity

Re: Alert: Human Cell and Tissue Products

The Centers for Medicare & Medicaid Services (CMS), in collaboration with the Investigations Medicare Drug Integrity Contractor (I-MEDIC), has been made aware of questionable billing for several Q codes related to amniotic tissue injections using human cell and tissue products. The amniotic tissue products are included in the Healthcare Common Procedure Coding System (HCPCS) code range of Q41XX and Q42XX.

CMS has seen a significant increase of billing in these products for indications other than wound healing in original Medicare and in the Medicare Advantage program. CMS is providing this information to your organization in order to aid your compliance programs in accordance with Chapter 21¹ of the *Medicare Managed Care Manual*.

Figure 1. Total Claim Count for Select Q Codes by Quarter in Medicare Advantage



¹ *Medicare Managed Care Manual*, Chapter 21 Compliance Program Guidelines

<https://www.cms.gov/medicare/prescription-drug-coverage/prescriptiondrugcovcontra/downloads/chapter9.pdf>

Accessed on July 20, 2021.

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The Medicare program provides coverage for amniotic tissue products that are typically used for wound healing. While no National Coverage Determination is currently active for these products, there are several Local Coverage Determinations and Local Coverage Articles including:

- **L35041:² Local Coverage Determination (LCD):**
Application of Bioengineered Skin Substitutes to Lower Extremity Chronic Non-Healing Wounds
- **L36690:³ Local Coverage Determination (LCD):**
Wound Application of Cellular and/or Tissue Based Products (CTPs), Lower Extremities
- **L36377:⁴ Local Coverage Determination (LCD):**
Application of Skin Substitute Grafts for Treatment of DFU and VLU of Lower Extremities
- **A56155:⁵ Local Coverage Article:**
Use of Amniotic Membrane Derived Skin Substitutes
- **A56156:⁶ Local Coverage Article:**
Use of Amniotic Membrane Derived Skin Substitutes

The Food and Drug Administration (FDA) issued a consumer alert⁷ in July 2020, which noted that amniotic tissue products were not approved for the treatment of any orthopedic conditions, including osteoarthritis, tendonitis, disc disease, tennis elbow, back pain, hip pain, knee pain, neck pain, or shoulder pain.

Through original Medicare, CMS has noted providers using various tendon, trigger point, and joint

² Centers for Medicare & Medicaid Services, Medicare Coverage Database, Local Coverage Determination (LCD): Application of Bioengineered Skin Substitutes to Lower Extremity Chronic Non-Healing Wounds <https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=35041&ver=113&Date=&DocID=L35041&bc=iAAAABAAAA&> Accessed on July 22, 2021.

³ Centers for Medicare & Medicaid Services, Medicare Coverage Database, Local Coverage Determination (LCD): Wound Application of Cellular and/or Tissue Based Products (CTPs), Lower Extremities <https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=36690&ver=29&Date=&DocID=L36690&bc=iAAAABAAAA&> Accessed on July 22, 2021.

⁴ Centers for Medicare & Medicaid Services, Medicare Coverage Database, Local Coverage Determination (LCD): Application of Skin Substitute Grafts for Treatment of DFU and VLU of Lower Extremities <https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=36377&ver=7&DocID=L36377&bc=gAAAABAAAA&> Accessed on July 22, 2021.

⁵ Centers for Medicare & Medicaid Services, Medicare Coverage Database, Local Coverage Article: Use of Amniotic Membrane Derived Skin Substitutes <https://www.cms.gov/medicare-coverage-database/details/article-details.aspx?articleId=56155&ver=3&DocID=A56155&bc=gAAAABAAAA&> Accessed on July 22, 2021.

⁶ Centers for Medicare & Medicaid Services, Medicare Coverage Database, Local Coverage Article: Use of Amniotic Membrane Derived Skin Substitutes (A56156) <https://www.cms.gov/medicare-coverage-database/details/article-details.aspx?articleId=56156&ver=3&DocID=A56156&bc=gAAAABAAAA&> Accessed on July 22, 2021.

⁷ U.S. Food and Drug Administration, Consumer Alert on Regenerative Medicine Products Including Stem Cells and Exosomes <https://www.fda.gov/vaccines-blood-biologics/consumers-biologics/consumer-alert-regenerative-medicine-products-including-stem-cells-and-exosomes> Accessed on July 20, 2021.

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injections on the same date of service as amniotic tissue products. The use of amniotic tissue products for the treatment of pain would be considered off-label and not covered by original Medicare.

Appendix B identifies the Current Procedure Terminology (CPT) codes for pain injections that have been billed on the same date of service as amniotic tissue products in original Medicare. Original Medicare has placed payment edits on claims billed with amniotic tissue products and pain injections on the same date of service.

CMS has also noted diagnosis codes utilized which indicate the treatment of orthopedic conditions billed along with the amniotic tissue products in both original Medicare and Medicare Advantage programs. Many of these International Classification of Diseases (ICD) 10 codes are in the range of MXX, which include diseases of the musculoskeletal system and connective tissue.

As noted previously, Medicare provides coverage of amniotic tissue products for wound healing. The use of amniotic tissue products for the treatment of pain would be considered off-label and not covered by original Medicare.

This information is being provided to your organization in order to aid in your efforts to combat fraud, waste, and abuse within your Medicare Advantage program.

Please report your vetted complaints to the I-MEDIC using the referral form located at <https://www.qlarant.com/about/contracts>. The I-MEDIC may also be reached at 1-877-7SAFERX (1-877-772-3379).

If your organization has questions on this matter, please contact your CMS Account Manager or Bill Roland of the I-MEDIC at rolandb@qlarant.com.

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Appendix A. Select Q Codes included in Figure 1

<i>HCPCS Code</i>	<i>HCPCS Code Description</i>
Q4145	Epifix, injectable, 1mg
Q4155	Neoxflo or clarixflo 1 mg
Q4162	Woundex flow, bioskin flow, 0.5cc
Q4171	Interfyl, 1 mg
Q4174	Palingen or promatrx, 0.36 mg per 0.25 cc
Q4177	Floweramnioflo, 0.1 cc
Q4185	Cellesta flowable amnion (25 mg per cc); per 0.5cc
Q4192	Restorigin, 1 cc
Q4206	Fluid flow or fluid gf, 1 cc
Q4213	Ascent, 0.5 mg
Q4215	Axolotl ambient or axolotl cryo, 0.1 mg
Q4231	Corplex p, per cc

Appendix B. Current Procedural Terminology Codes for Pain Injections

<i>CPT Code</i>	<i>CPT Code Description</i>
20550	Injection(s), single tendon sheath
20551	Injection(s), single tendon origin
20552	Injection(s), single or multiple trigger point(s), 1 or 2 muscle(s)
20553	Injection(s), single or multiple trigger point(s), 3 or more muscle(s)
20600	Arthrocentesis, aspiration and/or injection, small joint or bursa (e.g., fingers, toes); without ultrasound guidance
20604	Arthrocentesis, aspiration and/or injection, small joint or bursa (e.g., fingers, toes); with ultrasound guidance, with permanent recording and reporting
20605	Arthrocentesis, aspiration and/or injection, intermediate joint or bursa (e.g., temporomandibular, acromioclavicular, wrist, elbow or ankle, olecranon bursa); without ultrasound guidance
20606	Arthrocentesis, aspiration and/or injection, intermediate joint or bursa (e.g., temporomandibular, acromioclavicular, wrist, elbow or ankle, olecranon bursa); with ultrasound guidance, with permanent recording and reporting
20610	Arthrocentesis, aspiration and/or injection, major joint or bursa (e.g., shoulder, hip, knee, subacromial bursa); without ultrasound guidance
20611	Arthrocentesis, aspiration and/or injection, major joint or bursa (e.g., shoulder, hip, knee, subacromial bursa); with ultrasound guidance, with permanent recording and reporting

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