



Navigating Market Access with Magnolia

**Cracking the Code: Developing and
Implementing Coding Strategies for
Your Product**

September 24, 2026



a medical knowledge group company

Navigating Market Access with Magnolia

Today's Moderators and Speakers



Amanda Forys
Managing Partner,
Magnolia Market Access



Amanda O'Hora
Senior Vice President,
Market Access & Reimbursement

Agenda

1

Why You Need a Coding Strategy

2

Overview of Key Coding Systems in the U.S.

3

Coding Strategy Considerations

4

The Pets of MMA

Why You Need a Coding Strategy

Why You Need a Coding Strategy: Payer and Provider Education

Billing Guides



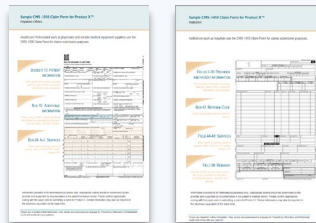
Coding Tip Sheets



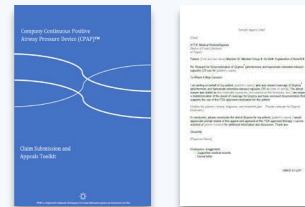
Educational Videos



Sample Claim Forms



Appeal Toolkits



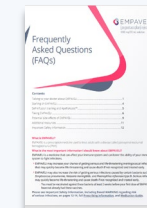
Hub Communications



ASP Rate Cards



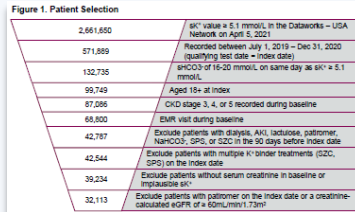
Training and FAQs



ASP, average sales price; FAQs, frequently asked questions

Why You Need a Coding Strategy: HEOR and RWE Studies and Models

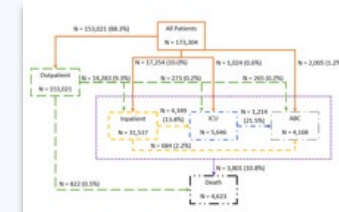
Patient Selection for Trials



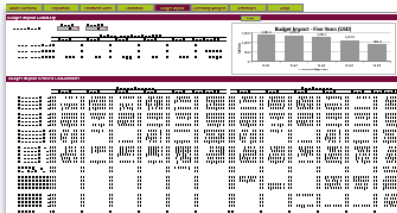
Label Expansion



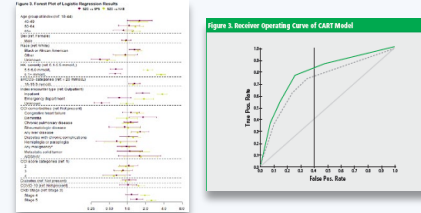
Patient Journey



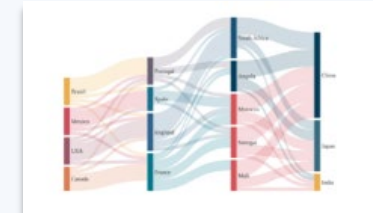
Budget Impact Models



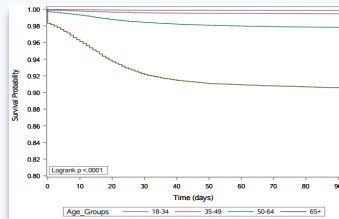
Predictive Models



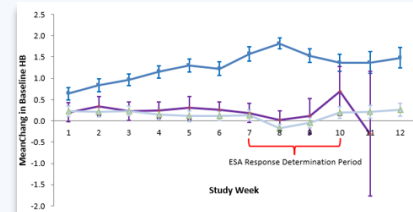
Treatment Pathways



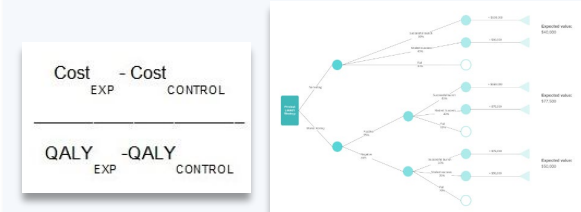
Time-to-Event



Comparative Effectiveness



CEA and CEM



CEA, cost-effectiveness analysis, CEM, cost-effectiveness model

Why You Need a Coding Strategy: People Make Mistakes...



Turalio™ (pexidartinib)
(Oral)

Document Number: IC-0489

Last Review Date: 04/06/2021
Date of Origin: 09/03/2019
Dates Reviewed: 09/2019, 02/2020, 04/2021

I. Length of Authorization

- Coverage will be provided for six months and may be renewed.

II. Dosing Limits

A. Quantity Limit (max daily dose) [NDC Unit]:

- Turalio 200 mg capsules: 4 capsules per day

B. Max Units (per dose and over time) [HCPCS Unit]:

- 800 mg per day

III. Initial Approval Criteria ¹

Coverage is provided in the following conditions:

- Patient is at least 18 years of age: **AND**

Universal Criteria ¹⁻⁴

- Patient does not have any pre-existing active liver or biliary tract disease: **AND**
- Patient and provider are enrolled in the Turalio Risk Evaluation and Mitigation Strategy (REMS) Program: **AND**
- Patient will avoid concomitant use with the following drugs:
 - Strong CYP3A inducers (e.g., rifampin, carbamazepine, St. John's Wort, etc.): **AND**
 - Moderate or strong CYP3A inhibitors (e.g., fluconazole, itraconazole, grapefruit juice, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented: **AND**
 - UGT inhibitors (e.g., probenecid, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented: **AND**
 - Acid reducing agents (e.g., proton pump inhibitors, etc.): **AND**

Proprietary & Confidential
© 2021 Magellan Health, Inc.

MagellanRx
MANAGEMENT

Tenosynovial Giant Cell Tumor (TGCT) † Φ ¹⁻⁴

- Patient has a histologically confirmed diagnosis of TGCT [also referred to as giant cell tumor of the tendon sheath (GCT-TS) or pigmented villonodular synovitis (PVNS)]; **AND**
- Will be used as single-agent therapy

Histiocytic Neoplasms † ^{2,4,6}

- Used for disease with colony stimulating factor 1 receptor (CSF 1R) mutation target: **AND**
- Will be used as single-agent therapy: **AND**
- Patient has one of the following sub-types of disease:
 - Langerhans Cell Histiocytosis (LCH): **AND**
 - Used for multisystem disease with symptomatic or impending organ dysfunction: **OR**
 - Used for pulmonary LCH: **OR**
 - Patient has multifocal single system bone disease not responsive to treatment with a bisphosphonate and more than 2 lesions: **OR**
 - Patient has CNS lesions: **OR**
 - Used for relapsed/refractory disease: **OR**
 - Erdheim-Chester Disease: **AND**
 - Patient has symptomatic disease: **OR**
 - Used for relapsed or refractory disease: **OR**
 - Rosai-Dorfman Disease: **AND**
 - Patient has symptomatic disease that is multifocal or unresectable unifocal: **OR**
 - Used for relapsed or refractory disease

† FDA Approved Indication(s); ‡ Compendia recommended indication(s); Φ Orphan Drug

IV. Renewal Criteria ¹

Coverage may be renewed based on the following criteria:

- Patient continues to meet universal and other indication-specific relevant criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc. identified in section III: **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: severe hepatotoxicity, etc.: **AND**
- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread or improvement in patient symptoms and/or functional status: **AND**
- Patient does not have any of the following signs of hepatotoxicity:
 - Increased ALT and/or AST >3 times the upper limit of normal: **OR**
 - Increase in both alkaline phosphatase and GGT >2 times the upper limit of normal: **OR**
 - Increased total bilirubin above the upper limit of normal

Page 2 |

TURALIO™ (pexidartinib) Prior Auth Criteria
Proprietary Information. Restricted Access – Do not disseminate or copy without approval.
© 2021 Magellan Rx Management

MagellanRx
MANAGEMENT

6. Durham BH, Lopez-Rodrigo E, Picarsic J, et al. Activating mutations in CSF1R and additional receptor tyrosine kinases in histiocytic neoplasms. Nat Med 2019;25:1839-1842.

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
C49.8	Malignant neoplasm of overlapping sites of connective and soft tissue
C49.9	Malignant neoplasm of connective and soft tissue, unspecified
C49.10	Malignant neoplasm of connective and soft tissue of unspecified upper limb, including shoulder
C49.11	Malignant neoplasm of connective and soft tissue of right upper limb, including shoulder
C49.12	Malignant neoplasm of connective and soft tissue of left upper limb, including shoulder
C49.20	Malignant neoplasm of connective and soft tissue of unspecified lower limb, including hip
C49.21	Malignant neoplasm of connective and soft tissue of right lower limb, including hip
C49.22	Malignant neoplasm of connective and soft tissue of left lower limb, including hip
C96.0	Multifocal and multisystemic (disseminated) Langerhans-cell histiocytosis
C96.5	Multifocal and unisystemic Langerhans-cell histiocytosis
C96.6	Unifocal Langerhans-cell histiocytosis
C96.9	Malignant neoplasm of lymphoid, hematopoietic and related tissue, unspecified
D48.1	Neoplasm of uncertain behavior of connective and other soft tissue
D76.3	Other histiocytosis syndromes
Z85.831	Personal history of malignant neoplasm of soft tissue

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD), Local Coverage Determinations (LCDs), and Local Coverage Articles (LCAs) may exist and compliance with these policies is required where applicable. They can be found at: http://www.cms.gov/medicare/coverage/database/search/advanced_search.aspx. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD/LCA): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	Applicable State/US Territory	Contractor
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.

Page 4 |

TURALIO™ (pexidartinib) Prior Auth Criteria
Proprietary Information. Restricted Access – Do not disseminate or copy without approval.
© 2021, Magellan Rx Management

MagellanRx
MANAGEMENT

Why You Need a Coding Strategy: People Make Mistakes...



Turalio™ (pexidartinib) (Oral)

Last Review Date: 04/06/2021
Date of Origin: 09/03/2019
Dates Reviewed: 09/2019, 02/2020, 04/2021

Document Number: IC-0489

I. Length of Authorization

- Coverage will be provided for six months and may be renewed.

II. Dosing Limits

A. Quantity Limit (max daily dose) [NDC Unit]:

- Turalio 200 mg capsules: 4 capsules per day

B. Max Units (per dose and over time) [HCPCS Unit]:

- 800 mg per day

III. Initial Approval Criteria¹

Coverage is provided in the following conditions:

- Patient is at least 18 years of age; AND

Universal Criteria^{2,4}

- Patient does not have any pre-existing active liver or biliary tract disease; AND
- Patient and provider are enrolled in the Turalio Risk Evaluation and Mitigation Strategy (REMS) Program; AND
- Patient will avoid concomitant use with the following drugs:
 - Strong CYP3A inducers (e.g., rifampin, carbamazepine, St. John's Wort, etc.); AND
 - Moderate or strong CYP3A inhibitors (e.g., fluconazole, itraconazole, grapefruit juice, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; AND
 - UGT inhibitors (e.g., probenecid, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; AND
 - Acid reducing agents (e.g., proton pump inhibitors, etc.); AND

Proprietary & Confidential
© 2021 MagellanRx Management, Inc.

MagellanRx
MANAGEMENT

Tenosynovial Giant Cell Tumor (TGCT) † Φ^{1,4}

- Patient has a histologically confirmed diagnosis of TGCT [also referred to as giant cell tumor of the tendon sheath (GCT-TS) or pigmented villonodular synovitis (PVNS)]; AND
- Will be used as single-agent therapy

Histiocytic Neoplasms †^{2,5,6}

- Used for disease with colony stimulating factor 1 receptor (CSF 1R) mutation target; AND
- Will be used as single-agent therapy; AND
- Patient has one of the following sub-types of disease:
 - Langerhans Cell Histiocytosis (LCH); AND
 - Used for multisystem disease with symptomatic or impending organ dysfunction; OR
 - Used for pulmonary LCH; OR
 - Patient has multifocal single system bone disease not responsive to treatment with a bisphosphonate and more than 2 lesions; OR
 - Patient has CNS lesions; OR
 - Used for relapsed/refractory disease; OR
 - Erdheim-Chester Disease; AND
 - Patient has symptomatic disease; OR
 - Used for relapsed or refractory disease; OR
 - Rosai-Dorfman Disease; AND
 - Patient has symptomatic disease that is multifocal or unresectable unifocal; OR
 - Used for relapsed or refractory disease

† FDA Approved Indication(s); ‡ Compendia recommended indication(s); Φ Orphan Drug

IV. Renewal Criteria¹

Coverage may be renewed based on the following criteria:

- Patient continues to meet universal and other indication-specific relevant criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc. identified in section III; AND
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: severe hepatotoxicity, etc.; AND
- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread or improvement in patient symptoms and/or functional status; AND
- Patient does not have any of the following signs of hepatotoxicity:
 - Increased ALT and/or AST >3 times the upper limit of normal; OR
 - Increase in both alkaline phosphatase and GGT >2 times the upper limit of normal; OR
 - Increased total bilirubin above the upper limit of normal

Page 2 | TURALIO™ (pexidartinib) Prior Auth Criteria
Proprietary Information. Restricted Access – Do not disseminate or copy without approval.
© 2021 MagellanRx Management, Inc.

MagellanRx
MANAGEMENT

6. Durham BH, Lopez-Rodrigo E, Picarsic J, et al. Activating mutations in CSF1R and additional receptor tyrosine kinases in histiocytic neoplasms. Nat Med 2019;25:1839-1842.

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
C49.8	Malignant neoplasm of overlapping sites of connective and soft tissue
C49.9	Malignant neoplasm of connective and soft tissue, unspecified
C49.10	Malignant neoplasm of connective and soft tissue of unspecified upper limb, including shoulder
C49.11	Malignant neoplasm of connective and soft tissue of right upper limb, including shoulder
C49.12	Malignant neoplasm of connective and soft tissue of left upper limb, including shoulder
C49.20	Malignant neoplasm of connective and soft tissue of unspecified lower limb, including hip
C49.21	Malignant neoplasm of connective and soft tissue of right lower limb, including hip
C49.22	Malignant neoplasm of connective and soft tissue of left lower limb, including hip

Tenosynovial Giant Cell Tumor (TGCT) † Φ^{1,4}

- Patient has a histologically confirmed diagnosis of TGCT [also referred to as giant cell tumor of the tendon sheath (GCT-TS) or pigmented villonodular synovitis (PVNS)]; AND
- Will be used as single-agent therapy

Histiocytic Neoplasms †^{2,5,6}

- Used for disease with colony stimulating factor 1 receptor (CSF 1R) mutation target; AND
- Will be used as single-agent therapy; AND
- Patient has one of the following sub-types of disease:
 - Langerhans Cell Histiocytosis (LCH); AND
 - Used for multisystem disease with symptomatic or impending organ dysfunction; OR
 - Used for pulmonary LCH; OR
 - Patient has multifocal single system bone disease not responsive to treatment with a bisphosphonate and more than 2 lesions; OR
 - Patient has CNS lesions; OR
 - Used for relapsed/refractory disease; OR
 - Erdheim-Chester Disease; AND
 - Patient has symptomatic disease; OR
 - Used for relapsed or refractory disease; OR
 - Rosai-Dorfman Disease; AND
 - Patient has symptomatic disease that is multifocal or unresectable unifocal; OR
 - Used for relapsed or refractory disease

† FDA Approved Indication(s); ‡ Compendia recommended indication(s); Φ Orphan Drug

Why You Need a Coding Strategy: People Make Mistakes...



Turalio™ (pexidartinib) (Oral)

Document Number: IC-0489

Last Review Date: 04/06/2021
Date of Origin: 09/03/2019
Dates Reviewed: 09/2019, 02/2020

I. Length of Authorization

- Coverage will be provided for up to 12 months.

II. Dosing Limits

A. Quantity Limit (max d

- Turalio 200 mg capsules

B. Max Units (per dose a

- 800 mg per day

III. Initial Approval Criteria

Coverage is provided in

- Patient is at least 18 years of age.

Universal Criteria ¹⁻⁴

- Patient does not have any of the following conditions:
- Patient and provide (REMS) Program: A
- Patient will avoid c

 - Strong CYP3A
 - Moderate or str
 - etc.), or if there
 - reaction and/or
 - UGT inhibitors
 - monitored close
 - AND
 - Acid reducing a

Proprietary & Confidential
© 2021 Magellan Health, Inc.

Tenosynovial Giant Cell Tumor (TGCT) [†] Φ ¹⁻⁴

- Patient has a histologically confirmed diagnosis of TGCT [also referred to as giant cell tumor of the tendon sheath (GCT-TS) or pigmented villonodular synovitis (PVNS)]; AND
- Will be used as single-agent therapy

Histiocytic Neoplasms [†] ^{1,4,6}

- Used for disease with colony stimulating factor 1 receptor (CSF 1R) mutation target; AND
- Will be used as single-agent therapy; AND

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
C49.8	Malignant neoplasm of overlapping sites of connective and soft tissue
C49.9	Malignant neoplasm of connective and soft tissue, unspecified
C49.10	Malignant neoplasm of connective and soft tissue of unspecified upper limb, including shoulder
C49.11	Malignant neoplasm of connective and soft tissue of right upper limb, including shoulder
C49.12	Malignant neoplasm of connective and soft tissue of left upper limb, including shoulder
C49.20	Malignant neoplasm of connective and soft tissue of unspecified lower limb, including hip
C49.21	Malignant neoplasm of connective and soft tissue of right lower limb, including hip
C49.22	Malignant neoplasm of connective and soft tissue of left lower limb, including hip
C96.0	Multifocal and multisystemic (disseminated) Langerhans-cell histiocytosis
C96.5	Multifocal and unisystemic Langerhans-cell histiocytosis
C96.6	Unifocal Langerhans-cell histiocytosis
C96.9	Malignant neoplasm of lymphoid, hematopoietic and related tissue, unspecified
D48.1	Neoplasm of uncertain behavior of connective and other soft tissue
D76.3	Other histiocytosis syndromes
Z85.831	Personal history of malignant neoplasm of soft tissue

6. Durham BH, Lopez-Rodrigo E, Picarsic J, et al. Activating mutations in CSF1R and additional receptor tyrosine kinases in histiocytic neoplasms. Nat Med 2019;25:1839-1842.

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
C49.8	Malignant neoplasm of overlapping sites of connective and soft tissue
C49.9	Malignant neoplasm of connective and soft tissue, unspecified
C49.10	Malignant neoplasm of connective and soft tissue of unspecified upper limb, including shoulder
C49.11	Malignant neoplasm of connective and soft tissue of right upper limb, including shoulder
C49.12	Malignant neoplasm of connective and soft tissue of left upper limb, including shoulder
C49.20	Malignant neoplasm of connective and soft tissue of unspecified lower limb, including hip
C49.21	Malignant neoplasm of connective and soft tissue of right lower limb, including hip
C49.22	Malignant neoplasm of connective and soft tissue of left lower limb, including hip
C96.0	Multifocal and multisystemic (disseminated) Langerhans-cell histiocytosis
C96.5	Multifocal and unisystemic Langerhans-cell histiocytosis
C96.6	Unifocal Langerhans-cell histiocytosis
C96.9	Malignant neoplasm of lymphoid, hematopoietic and related tissue, unspecified
D48.1	Neoplasm of uncertain behavior of connective and other soft tissue
D76.3	Other histiocytosis syndromes
Z85.831	Personal history of malignant neoplasm of soft tissue

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD), Local Coverage Determinations (LCDs), and Local Coverage Articles (LCAs) may exist and compliance with these policies is required where applicable. They can be found at: http://www.cms.gov/medicare/coverage/database/search/advanced_search.aspx. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD/LCA): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	Applicable State/US Territory	Contractor
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.

TURALIO™ (pexidartinib) Prior Auth Criteria
Proprietary Information. Restricted Access – Do not disseminate or copy without approval.
© 2021, Magellan Rx Management

Page 4 |

MagellanRx
MANAGEMENT

Source: MagellanRx Management. Turalio™ (pexidartinib) (Oral) Prior Auth Criteria.

Why You Need a Coding Strategy: People Make Mistakes...

Code	Code Description
M12.20	Villonodular synovitis (pigmented), unspecified site
M12.211	Villonodular synovitis (pigmented), right shoulder
M12.212	Villonodular synovitis (pigmented), left shoulder
M12.219	Villonodular synovitis (pigmented), unspecified shoulder
M12.221	Villonodular synovitis (pigmented), right elbow
M12.222	Villonodular synovitis (pigmented), left elbow
M12.229	Villonodular synovitis (pigmented), unspecified elbow
M12.231	Villonodular synovitis (pigmented), right wrist
M12.232	Villonodular synovitis (pigmented), left wrist
M12.239	Villonodular synovitis (pigmented), unspecified wrist
M12.241	Villonodular synovitis (pigmented), right hand
M12.242	Villonodular synovitis (pigmented), left hand

Code	Code Description
M12.249	Villonodular synovitis (pigmented), unspecified hand
M12.251	Villonodular synovitis (pigmented), right hip
M12.252	Villonodular synovitis (pigmented), left hip
M12.259	Villonodular synovitis (pigmented), unspecified hip
M12.261	Villonodular synovitis (pigmented), right knee
M12.262	Villonodular synovitis (pigmented), left knee
M12.269	Villonodular synovitis (pigmented), unspecified knee
M12.271	Villonodular synovitis (pigmented), right ankle and foot
M12.272	Villonodular synovitis (pigmented), left ankle and foot
M12.279	Villonodular synovitis (pigmented), unspecified ankle and foot
M12.28	Villonodular synovitis (pigmented), other specified site
M12.29	Villonodular synovitis (pigmented), multiple sites

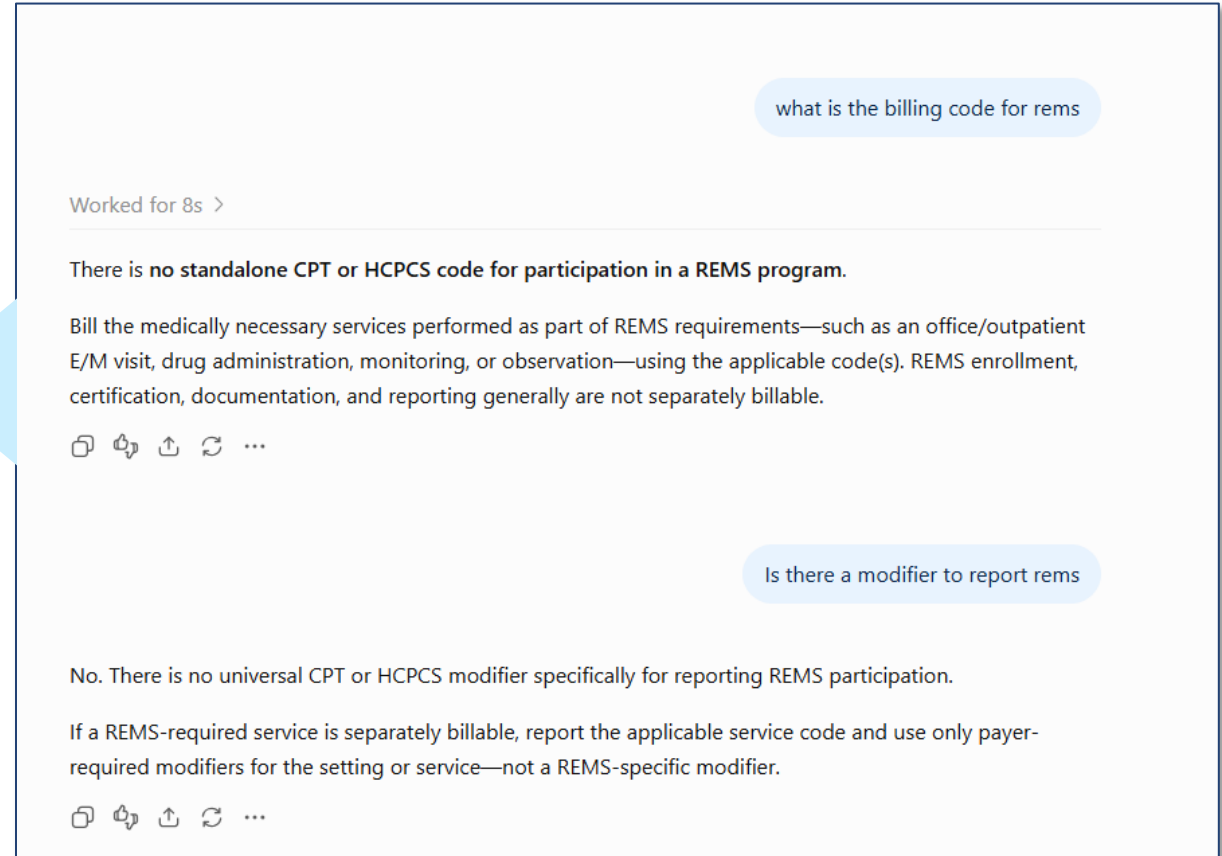
And It's Not Just People Making Mistakes...

- AI is a great tool, but it doesn't always get it right either...

HCPCS Modifier

RE Furnished in full compliance with FDA-mandated risk evaluation and mitigation strategy (REMS)

- AI is a good place to start and a good way to check your findings, but complete reliance on AI is risky



what is the billing code for reme

Worked for 8s >

There is **no standalone CPT or HCPCS code for participation in a REMS program.**

Bill the medically necessary services performed as part of REMS requirements—such as an office/outpatient E/M visit, drug administration, monitoring, or observation—using the applicable code(s). REMS enrollment, certification, documentation, and reporting generally are not separately billable.

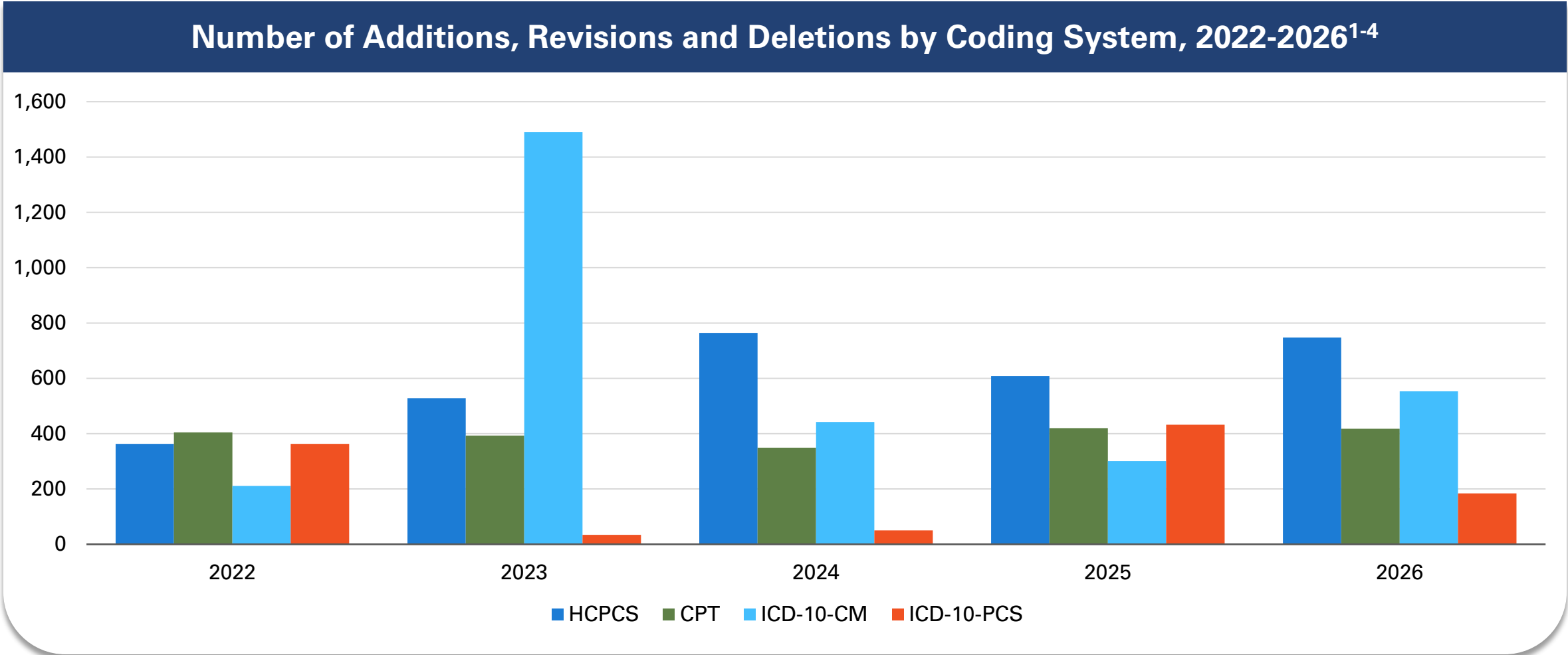
Is there a modifier to report reme

No. There is no universal CPT or HCPCS modifier specifically for reporting REMS participation.

If a REMS-required service is separately billable, report the applicable service code and use only payer-required modifiers for the setting or service—not a REMS-specific modifier.

Sources: 1. OpenAI. (September 4, 2026). ChatGPT. 2. CMS. Healthcare Common Procedure Coding System (HCPCS) Level II Coding Procedures CMS. HCPCS Quarterly Update (October 2026).

Why You Need a Coding Strategy: Codes Change



Sources: 1. CMS. HCPCS Quarterly Files Jan/Apr/Jul/Oct 2022-2026. 2. AMA. New CPT Code Set Press Releases 2022-2026. 3. AAPC. What's New for ICD-10-CM. 2022-2026. 4. CMS. FY 2022-2026 ICD-10-PCS Update Summaries.

Overview of Key Coding Systems in the U.S.

Healthcare Common Procedure Coding System (HCPCS)

- Centers for Medicare and Medicaid Services (CMS) maintains HCPCS codes through the HCPCS Workgroup
- Represent drugs, medical devices, supplies, and procedures/professional services

Code	Code Description	Comments
C9310	Injection, leucovorin calcium (avyxa), 1 mg	For pass-through status
J1442	Injection, filgrastim (g-CSF), excludes biosimilars, 1 microgram	Product specific
J3490	Unclassified drugs	Not product specific
J8499	Prescription drug, oral, non chemotherapeutic, NOS	Not product specific, but approach specific
Q2041	Axicabtagene ciloleucel, up to 200 million autologous anti-cd19 car positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose	Includes manufacturing steps

Current Procedural Terminology (CPT)

- The American Medical Association (AMA) maintains CPT codes using an Editorial Panel that votes on all decisions
 - Various physician specialty societies serve in an advisory capacity to the Editorial Panel
- Describe medical services and procedures performed by physicians and other qualified healthcare professionals

Code	Code Description	Comments
96372	Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular	Not product specific, but product type and approach specific
96413	Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug	Product type, approach, and timing specific

International Classification of Diseases, 10th Revision, Clinical Modification (ICD-10-CM)

- The National Center for Health Statistics (NCHS) maintains ICD-10-CM codes
- Identify diseases, conditions, symptoms, disabilities, malformations/abnormalities, etc
 - Organized by body system or condition (eg, diseases of the respiratory system, neoplasms)

ICD-10-CM Code	Description	Comments
E11.9	Type 2 diabetes mellitus without complications	Single code
M05.742	Rheumatoid arthritis with rheumatoid factor of the left hand without organ or systems involvement	Signifies body part, side of the body, and other system involvement

International Classification of Diseases, 10th Revision, Procedure Coding System (ICD-10-PCS)^{1,2}

- CMS maintains ICD-10-PCS codes
- Identify procedures, services, and treatments provided in facilities (eg, inpatient hospital)
 - Each digit or character represents a specific value

ICD-10-PCS are organized using the following categories:

Character 1	Section
Character 2	Body System
Character 3	Root Operation
Character 4	Body Part
Character 5	Approach
Character 6	Device (Substance, Technology)
Character 7	Qualifier

ICD-10-PCS Code	Description	Comments
30243C0	Transfusion of Autologous Hematopoietic Stem/Progenitor Cells, Genetically Modified into Central Vein, Percutaneous Approach	Not product specific, but location and approach specific
XW0331B	Introduction of Anitocabtagene Autoleucel Immunotherapy into Peripheral Vein, Percutaneous Approach, New Technology Group 11	Signifies body part, approach, specific substance, and qualifier (NTAP)

Coding Strategy Considerations

What Codes Do You Need? Code Sets by Site of Care

Code Set	Description	Site of Care*			
		IP	OP	MD	PH
Healthcare Common Procedure Coding System (HCPCS)	Represents drugs, services, and supplies	X	✓	✓	X
Current Procedural Terminology (CPT)	Describes medical services and procedures performed by physicians	X	✓	✓	X
International Classification of Diseases, 10th Revision, Clinical Module (ICD-10-CM)	Reports diseases, conditions, neoplasms, injuries, and poisonings	✓	✓	✓	✓
International Classification of Diseases, 10th Revision, Procedure Coding System (ICD-10-PCS)	Classifies procedures performed in inpatient settings	✓	X	X	X

*Indicates site of care where code is accepted for reporting or required for coverage purposes.
Key: IP, inpatient; OP, outpatient; MD, physician office; PH, pharmacy (retail or specialty)

What Codes Do You Need? HCPCS Codes Recognized by Payer Type

Code Subset	Description	Medicare	Medicaid	Commercial
C Codes	Reports new technology devices, drugs, biologicals, and radiopharmaceuticals that have received transitional pass-through status under the Medicare Hospital Outpatient Prospective Payment System	✓	?	?
G Codes*	Identifies professional health care services and medical services that could otherwise be coded in CPT	✓	?	?
J Codes	Drugs (typically not orally administered)	✓	✓	✓
M Codes	Identifies professional health care services and medical services that could otherwise be coded in CPT	✓	?	?
Q Codes	Temporary codes	✓	✓	✓
S Codes	Temporary national codes (non-Medicare)	✗	✓	✓
T Codes	National codes established for state Medicaid agencies	✗	✓	?

*CMS does not have an application process for G codes, as they are established by CMS, typically through notice and comment rulemaking.

What Are the Requirements to Apply? Common Requirements



FDA Approval



Settings where product is used



Detailed product or technology description



Evidence of substantial clinical improvement



Publications (eg, clinical trial findings, disease state, economic data)



Evidence that product or technology is new



Utilization data



Codes that are currently being billed to report the product

When Should You Apply? Annual Timeline Summary¹⁻³

Code Set	Year 1												Year 2												Year 3
	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan
HCPCS	Application Deadline			Application Deadline			Application Deadline	Earliest Effective Date		Application Deadline	Earliest Effective Date		Earliest Effective Date			Earliest Effective Date									
CPT		Application Deadline				Application Deadline					Application Deadline for Next Cycle (Year 4)														Earliest Effective Date
ICD-10-PCS and CM						Application Deadline						Application Deadline				Effective Date for Previous Cycle							Earliest Effective Date		



Application Deadline



Earliest Effective Date



Application Deadline for Next Cycle (Year 4)



Effective Date for Previous Cycle

Sources: 1. CMS. MEARIS. 2. American Medical Association (AMA). CPT® Editorial Panel Process - AMA/Specialty Society RVS Update (RUC) Process. 3. CMS. ICD-10-CM Coordination and Maintenance Committee (Meeting Materials).

Summary



Coding is a key component of a successful market access strategy

- Facilitates appropriate coverage policy creation, claims adjudication and payment of your product
- Allows accurate identification of patients, products, diseases and interventions in claims analyses



Coding may change over time, and needs may vary by site of care and payer type

- May be added, revised or discontinued quarterly, semi-annually, or annually
- Regularly review educational resources, coverage policies, and study protocols for accuracy
- Apply for new, revised or request code deletions accordingly



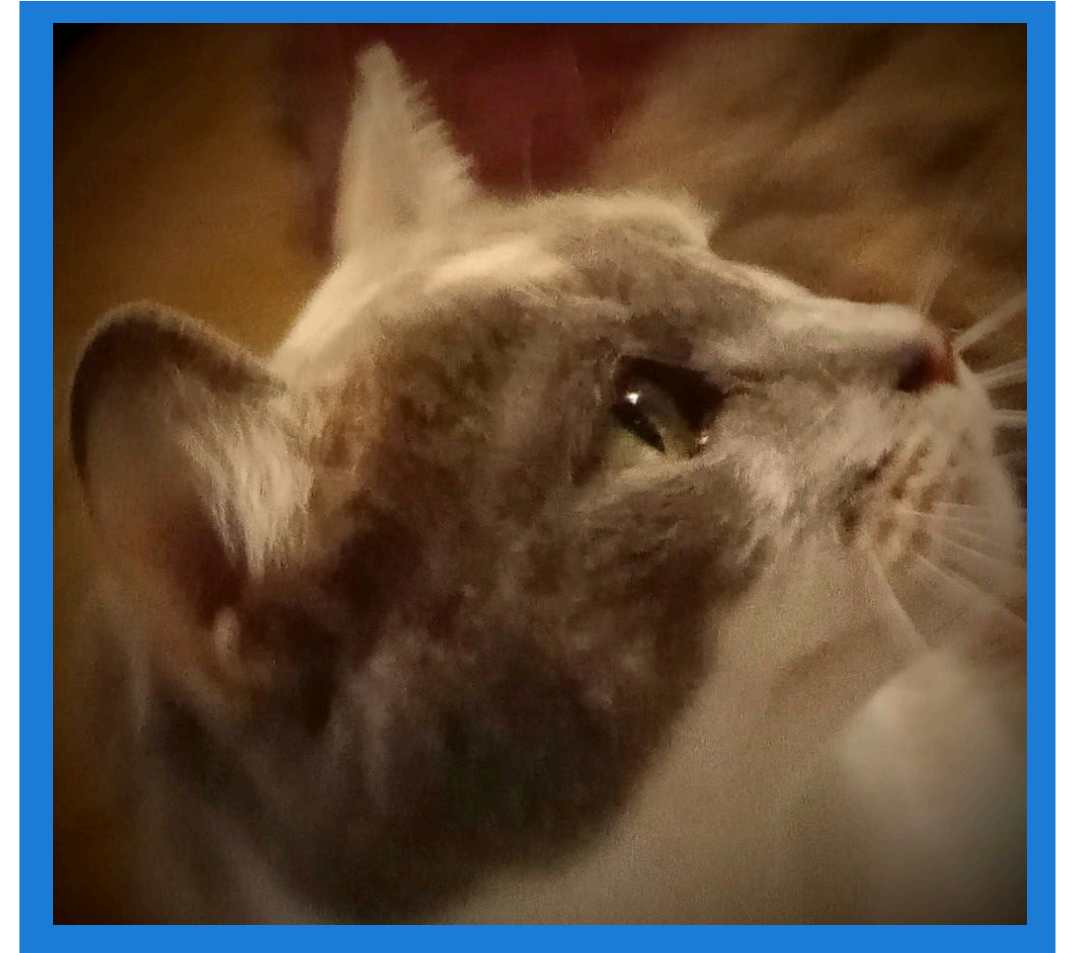
Customers and staff require education about codes for your product

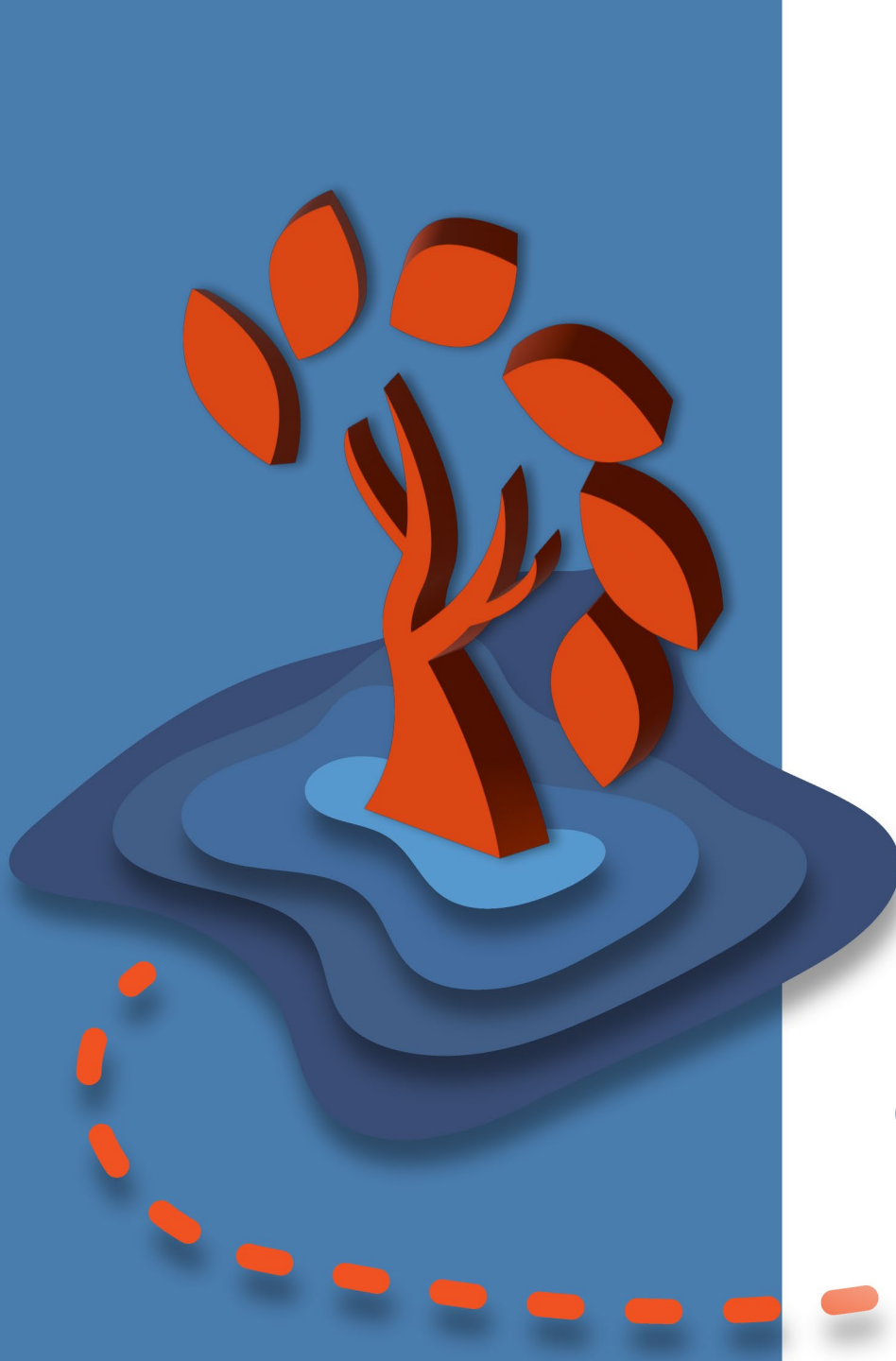
- Train staff responsible for discussing codes with customers
- Create educational materials that support the needs of your customers
- Modify study protocols to capture needed data

The Pets of MMA

Abigail (Abby)

- **Mother:** Amanda O'Hora
- **Age:** 10
- **Disposition:** Entitled princess
- **Likes:**
 - Fishy food
 - Chasing feathers, shredding cardboard, and digging up house plants
 - My human subjects that willingly do my bidding
- **Dislikes:**
 - When mom's office door is closed
 - Workmen in the house
- **Favorite Place to Sleep:** On top of the entertainment center (the best place to survey my kingdom)





Join us for our next

Navigating Market Access with Magnolia

From Evidence to Access: Understanding Payer Decisions and Rethinking Engagement

Thursday, October 29, 2026
12:00 - 1:00 PM Eastern

Connect With Us!

 linkedin.com/company/magnolia-market-access

 magnoliamarketaccess.com

Magnolia
market access
a medical knowledge group company

Confidential – Do Not Distribute