HOP Panel Presentation

Barricaid Bone-Anchored Implant (C9757)
Intrinsic Therapeutics

Presenters:

April Spillane, VP Health Economics, Intrinsic Therapeutics

Gail Daubert, Healthcare Consultant, Daubert Strategic Partners

August 2nd, 2024

Patients with Large Annular Defect Benefit from Procedure with Permanent Bone-Anchored Implant

**Barricaid is the <u>only</u> FDA Approved (PMA) Bone Anchored Annular Closure Device**

- Bone-anchored stability to withstand sheer forces and avoid migration
- Closes defect from inside the annulus with a physical barrier
- Significantly reduces a patient's risk of reoperation
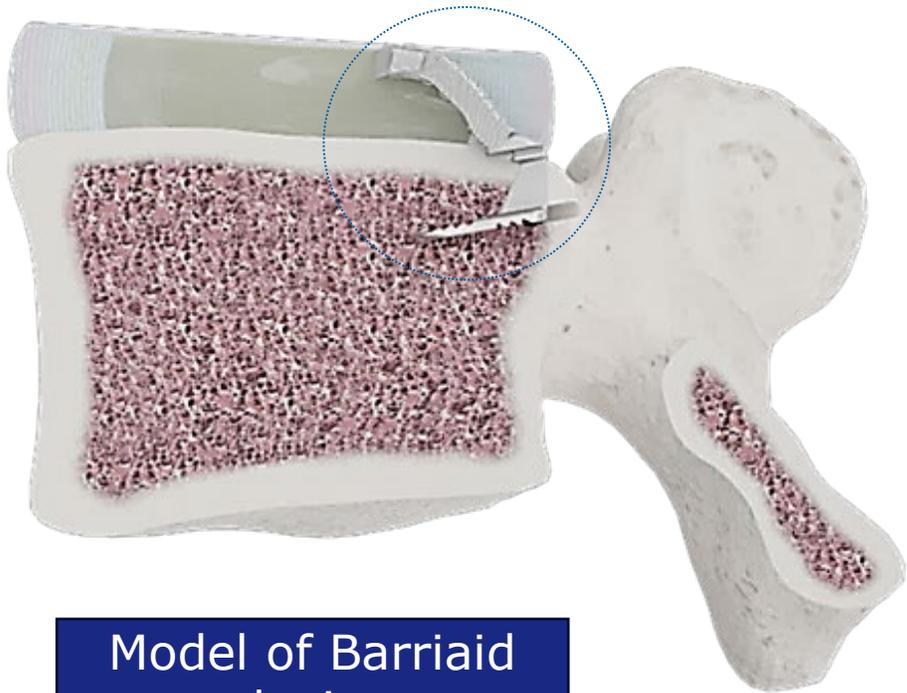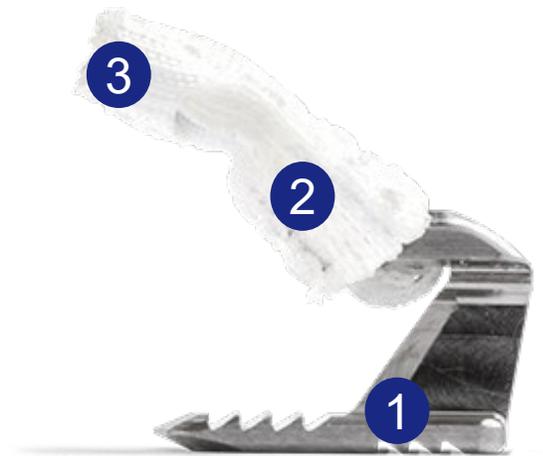
1. Titanium Bone Anchor
2. Flexible Barrier
3. Platinum-iridium Marker

Model of Barriaid device
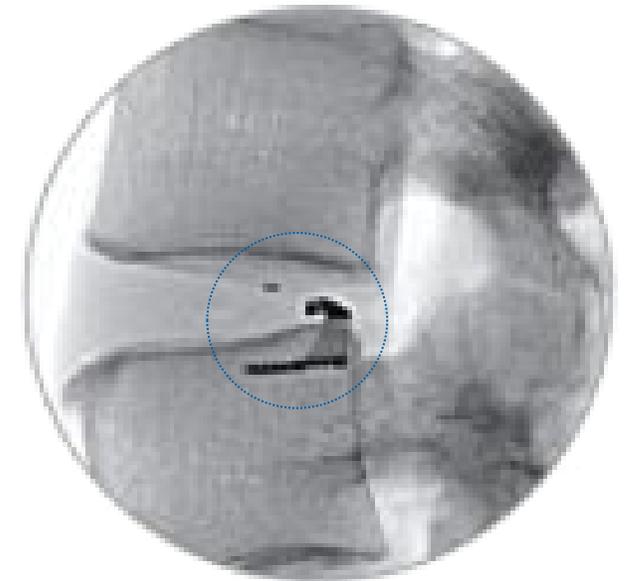
Fluoroscopic image Barriaid device

FDA PMA approved spinal implant

Barricaid® Approved Indications

- The Barricaid is **indicated for reducing the incidence of reherniation and reoperation** in skeletally mature patients with radiculopathy (with or without back pain) attributed to a posterior or posterolateral herniation, and confirmed by history, physical examination and imaging studies which demonstrate neural compression using MRI to treat a large annular defect (**between 4-6 mm tall and between 6-10 mm wide**) following a primary discectomy procedure (excision of herniated intervertebral disc) at a **single level between L4 and S1**.

CMS created C9757 – Effective January 2020

C9757 Describes the comprehensive procedure of the discectomy and repair of annular defect **with implantation of bone anchored annular closure device**, for Facility Billing:

- *C9757 Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and excision of herniated intervertebral disc, **and repair of annular defect with implantation of bone anchored annular closure device, including annular defect measurement, alignment and sizing assessment, and image guidance;** 1 interspace, lumbar.*

- **63030** *Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc; 1 interspace, lumbar*

Facility misreporting C9757 is negatively impacting beneficiary access

- We believe Hospitals are reporting wrong procedure code OR

- Using a non-bone anchored implant during a discectomy procedure to do something other than repair an annular defect

- Ongoing problem for 3+ year
  - Increasing in volume and frequency
  - More new sites misreporting each year

- Outreach by company to non-customers has resulted in facilities admitting inadvertent use of wrong procedure code

- Result of issue is 1) overpayments to hospitals and 2) negative impact on geometric mean cost calculation
  - concern for restricted access in future

Supporting Data

2025 Proposed Rule geometric mean cost calculations includes claims that did <u>not include </u>a bone anchored annular closure device

- Expert analysis of hospital outpatient claims data (by Watson Policy Analysis) over the last 3 years shows **more than half of the claims** submitted for C9757 have **no device charge reported**

- These same hospitals are <u>not customers of Intrinsic Therapeutics</u>, the manufacturer of the **only FDA approved bone anchored annular closure device**

- E.g. 2023 SAF files show that 18 out of the 40 providers that reported C9757, did <u>not report a device charge</u>

Recommendation: Device Edit for HCPCS procedure code C9757 to confirm use of bone anchored implant

We recommend a device edit be put in place

- E.g. Iris Implant

- Specifically, when a hospital reports HCPCS procedure code C9757 (assigned to rev code 0360), a device c-code (assigned to rev code 0278) is required to also be reported

- This should help:
  - Confirm the use of a bone anchored implant (required to perform procedure)
  - Eliminate incomplete claims that do not include a bone anchored annular closure device from being included in the geometric mean cost calculation for C9757.
  - Prevent future discectomy procedures (CPT 63030/APC 5114) from being overpaid by CMS.

Appendix
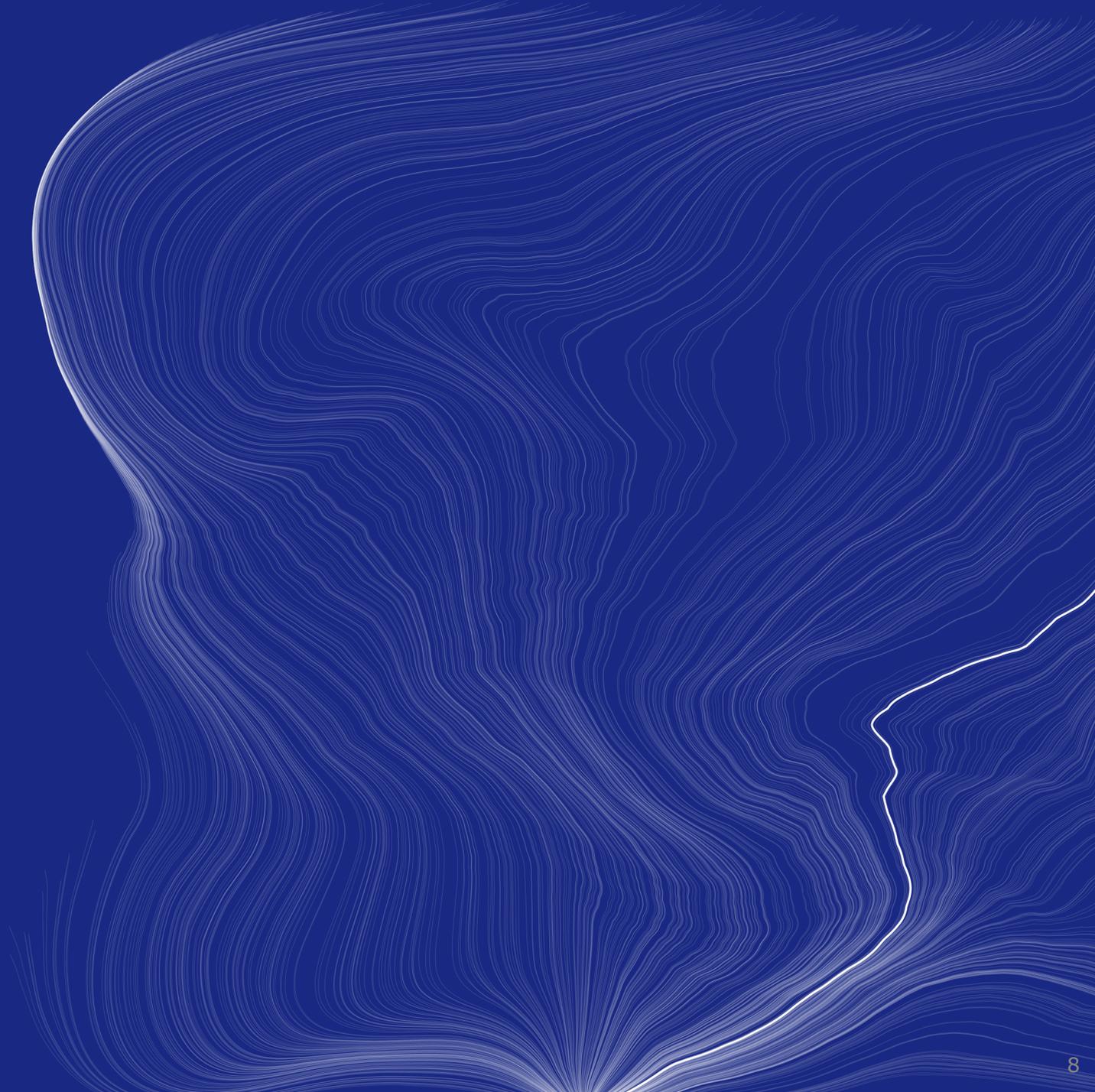
DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
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Baltimore, Maryland 21244-1850

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

November 5, 2019

Tom Michal
Vice President, Market Access, Health Economics & Reimbursement
Intrinsic Therapeutics
30 Commerce Way
Woburn, MA 01801

Dear Mr. Michal:

Thank you for submitting the application on behalf of Intrinsic Therapeutics for the lumbar discectomy with a bone-anchored implant procedure for consideration as a New Technology APC under Medicare's hospital outpatient prospective payment system (OPPS).

Based on the application, we have determined that the lumbar discectomy with a bone-anchored implant procedure does not meet the criteria for assignment to a New Technology APC for the following reason:

➤ The service can be reasonably placed in an existing APC group that is appropriate in terms of clinical characteristics and resource costs.

However, while we have not assigned this service to a new technology APC, based on our review of the clinical and resource characteristics of this service, we established the following HCPCS code effective January 1, 2020:

• HCPCS code C9757 *"Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and excision of herniated intervertebral disc, and repair of annular defect with implantation of bone anchored annular closure device, including annular defect measurement, alignment and sizing assessment, and image guidance; 1 interspace, lumbar."*

For CY 2020, the service described by HCPCS code C9757 has been assigned to a clinical APC. Please see Addendum A to the CY 2020 OPPS/ASC final rule with comment period for APC assignment.

Thank you for your application, and I hope this information is helpful.

Sincerely,

Tiffany Swygert
Director, Division of Outpatient Care