# 07.01.98 Annular Closure Devices

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### Related Policies:

- 07.01.87 Automated Percutaneous and Percutaneous Endoscopic Discectomy
- 07.01.90 Percutaneous Intradiscal Electrothermal Annuloplasty and Percutaneous Intradiscal Radiofrequency Annuloplasty
- 07.01.03 Artificial Intervertebral Disc
- 07.01.88 Decompression of the Intervertebral Disc Using Laser Energy (Laser Discectomy) or Radiofrequency-Coblation (Nucleoplasty)
- 08.01.18 Vertebral Axial Decompression

### Summary

### Description

Discectomy is a surgical procedure in which 1 or more intervertebral discs are removed. Extrusion of an intervertebral disc beyond the intervertebral space can compress the spinal nerves and result in pain, numbness, and weakness. Discectomy is intended to treat symptoms by relieving pressure on the

affected nerve root(s). Annular closure devices can be used following discectomy to reduce future herniation.

### Summary of Evidence

For individuals who have a lumbar herniated disc and undergo discectomy, use of a bone-anchored annular closure device has been evaluated as a means to reduce reherniation and reoperation in a systematic review and RCTs. Relevant outcomes are symptoms, functional outcomes, health status measures, quality of life, and treatment-related mortality and morbidity. Although a key RCT found beneficial effects in terms of reoperation and reherniation, the evidence is limited by a lack of blinding. In patients with lumbar radiculopathy with disc herniation who receive discectomy and an annular closure device, the evidence is insufficient evidence to determine that the technology results in an improvement in net health outcomes.

## OBJECTIVE

The objective of this evidence review is to determine whether the use of an annular closure device improves the net health outcome for individuals who have undergone discectomy for lumbar herniated discs.

## PRIOR APPROVAL

Not applicable

## POLICY

The use of an annular closure device following discectomy is considered **investigational** because the evidence is insufficient to determine the effects of this technology on net health outcomes.

## POLICY GUIDELINES

Lumbar discectomy refers to standard open discectomy or minimally invasive microdiscectomy. Annular closure devices are proposed to be used to reduce the risk of recurrence in patients with large annular defects following discectomy.

### Coding

See the Codes table for details.

## BACKGROUND

### Lumbar Disc Herniation

Extrusion of a lumbar intervertebral disc beyond the intervertebral space can compress the spinal nerves and result in symptoms of pain, numbness, and weakness.

The natural history of untreated disc herniations is not well-characterized, but most herniations will decrease in size over time due to shrinking and/or regression of the disc. Clinical symptoms will also tend to improve over time in conjunction with shrinkage or regression of the herniation.

## Treatment

### Conservative Therapy

Because most disc herniations improve over time, initial care is conservative, consisting of analgesics and a prescribed activity program tailored to patient considerations. Other potential nonsurgical interventions include opioid analgesics and chiropractic manipulation. Epidural steroid injections can also be used as a second-line intervention and are associated with short-term relief of symptoms. Rapidly progressing symptoms or continued symptoms with failure of conservative therapy may lead to surgical intervention.

### Discectomy

Lumbar discectomy is a surgical procedure in which the herniation (extrusion) of the intervertebral disc is removed. Discectomy is intended to treat symptoms by relieving pressure on the affected nerve(s). Lumbar discectomy can be performed by a variety of surgical approaches. Open discectomy is the traditional approach. In open discectomy, a 2- to 3-cm incision is made over the area to be repaired. The spinal muscles are dissected, and a portion of the lamina may be removed to allow access to the vertebral space. The extruded disc is removed either entirely or partially using direct visualization. Osteophytes that are protruding into the vertebral space can also be removed if deemed necessary.

The main alternative to open discectomy is microdiscectomy, which has gained popularity. Microdiscectomy is a minimally invasive procedure that involves a smaller incision, visualization of the disc through a special camera, and removal of disc fragments using special instruments. Because less resection can be performed in a microdiscectomy, it is usually reserved for smaller herniations, in which a smaller amount of tissue needs to be removed.

### Annular Closure Devices

Approximately 1 in 10 patients are reported to have a recurrence following discectomy. In patients with large annular defects following lumbar discectomy, annular closure devices have been proposed to reduce the risk of recurrence and reoperation. Although many devices and techniques have been investigated, a bone-anchored implant is the only device currently available that is approved by the Food and Drug Administration (FDA).

## Regulatory Status

Barricaid®, a bone-anchored annular closure device, was approved by the FDA in 2019 (PMA #P160050, Product Code=QES) for use in patients with large annular defects (4-6 mm tall and 6-10 mm wide) following a primary discectomy procedure at a single level between L4 and S1.

Other annular closure devices with U.S. Food and Drug Administration (FDA) 510(k) clearance for marketing by Annulex, the Inclose™ Surgical Mesh System (August 18, 2005) and the Xclose® Tissue Repair System (August 7, 2006) are no longer available in the U.S. Although the Disc Annular Repair

Technology (DART) System (Magellan Spine Technologies, Inc., Irvine, CA) received European CE Mark approval in 2009, it has not yet been cleared by FDA for use in the U.S.

## RATIONALE

This evidence review was created in October 2023 and has been updated regularly with searches of the PubMed database. The most recent literature update was performed through September 26, 2024.

Evidence reviews assess the clinical evidence to determine whether the use of technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life, and ability to function, including benefits and harms. Every clinical condition has specific outcomes that are important to patients and managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of technology, 2 domains are examined: the relevance, and quality and credibility. To be relevant, studies must represent 1 or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. RCTs are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

### *Clinical Context and Therapy Purpose*

The purpose of an annular closure device after lumbar discectomy is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The following PICO was used to select literature to inform this review.

### *Populations*

The relevant population of interest is individuals who are undergoing lumbar discectomy with large annular defects.

### *Interventions*

The therapy being considered is a bone-anchored annular closure device.
Annular closure devices are intended for use in large annular defects following discectomy.

### *Comparators*

The comparator of interest is lumbar discectomy without use of an annular closure device.

## *Outcomes*

The general outcomes of interest are symptoms, functional outcomes, health status measures, quality of life, treatment-related mortality, and treatment-related morbidity.

Outcome measures for back surgery are relatively well-established (Table 1). Most studies use back and leg visual analog scores (VAS) or the Zurich Claudication Questionnaire (ZCQ) to assess pain and the Oswestry Disability Index (ODI) to assess functional limitations related to back pain. Most studies also use a broader functional status index such as the Short Form (SF)-12 or SF-36, particularly the physical function subscale of SF-36. Throughout this report, we refer to a combination of pain and function measures as "Back and Leg Pain Measures." Determining the minimal clinically important difference (MCID) for these measures is complex. The MCID for a given measure can depend on the baseline score or severity of illness, the method used to calculate MCID, and the times at which the scores are measured (Katz 2015) For these reasons, some investigators prefer to calculate a minimum detectable difference (MDD)(Parker et al, 2012).

Both short- and long-term outcomes are important in evaluating back treatments (Katz, 2015). For example, for definitive back surgery, net benefit should take into account immediate (perioperative) adverse events; improvements in pain, neurological status, and function at 12 to 24 months as measured by the ODI, SF-36, ZCQ, or VAS measures; and 5-year secondary surgery rates, which reflect longer-term complications, recurrences, and treatment failures. In some trials, the epidural injection has been considered an event indicative of treatment failure. This is usually not appropriate. Instead, patient-reported outcomes should be measured at prespecified time intervals in all patients, whether or not they undergo injections or secondary procedures. When possible, trials should use explicit criteria for secondary surgeries or measure patient-reported outcomes just prior to secondary procedures so those implicit criteria for reoperation can be compared across studies.

**Table 1. Patient-reported Outcome Measures for Back and Leg Pain**

| Measure | Outcome Evaluated | Description | MDD and MCID |
|---|---|---|---|
| Oswestry Disability Index (ODI) | Functional disability and pain related to back conditions | Ten 5-point items; scores 0 (no disability) to 50 (totally disabled) or 0 to 100% of maximum score | MDD: 8 to 10 points<br>MCID varies; often 15 points (30 percentage points) |
| Zurich Claudication Questionnaire (ZCQ) | Pain, numbness, weakness, walking tolerance, and (if applicable) satisfaction with treatment results | 18 items; 3 subscales; total score is expressed in points or as a percentage of maximum score (higher scores are worse) | MDD: 5 points<br>MCID: Varies; sometimes defined as a detectable improvement on 2 of 3 subscales |
| Roland and Morris Disability Questionnaire (RMDQ) | Disability from back problems | 24 items; scored 0 to 24 (higher scores are worse) | MCID: 30% reduction |
| Visual analog scale for leg pain | Degree of leg pain | Patients indicate the degree of pain on a 0 to 100 scale | MDD: 5 points |
| Visual analog scale for back pain | Degree of back pain | Patients indicate the degree of pain on a 0 to 100 scale | MDD: 2 points |

## Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Consistent with a 'best available evidence approach,' within each category of study design, studies with larger sample sizes and longer durations were sought.
- Studies with duplicative or overlapping populations were excluded.

## Review of Evidence

### Systematic Reviews

Hayes,a symplr company completed a Health Technology Assessment (July 2025) regarding annular closure for prevention of lumbar disc reherniation specific to the Barricaid annular closure device (ACD). While the evidence may suggest the use of ACD implantation (Barricaid) as an adjunct to discectomy may provide some improvements in back pain, leg pain, quality of life and disc height relative to discectomy alone, this evidence was rated low due to limitations that included lack of randomization of patients to treatment groups, small study sizes, retrospective analysis, utilization of historical control group(s), high dropout rate and only included 2-years of follow-up in most of the studies. From a safety perspective based on the reviewed studies adverse events were considered generally mild-to-moderate, however, there were serious adverse events reported to include ACD failure (migration, detachment, or anchor failure), wound complications and lower extremity pain.

Miller et al (2020) published a systematic review and meta-analysis of the Barricaid annular device in patients at high risk for lumbar disc reherniation. Four trials (2 RCTs) were included in the meta-analysis (Table 2). Tables 3 and 4 summarize the characteristics and the results of the meta-analysis. The trial by Thomé et al (2018) summarized below was the only trial to find a significant decrease in symptomatic reherniation or reoperation at 2 years. The other 3 trials all indicated nonsignificant reduction for both outcomes. Overall, results of the meta-analysis favored the use of an annular device for post-discectomy patients with large annular defects.

Wang et al (2023) also conducted a meta-analysis of the Barricaid device. In addition to the 4 studies included in the Miller et al (2020) meta-analysis, Wang et al (2023), included an additional 129 participants from an additional 2 nonrandomized studies (Kurzbuch et al [2022] and Parker et al [2016]). Findings from the Wang et al (2023) pooled analysis of reherniation rate was consistent with that of Miller et al (2020) (OR, 0.45; 95% CI, 0.31-0.66). However, this finding should be interpreted with caution as follow-up in the additional studies was only 12 months in duration.

**Table 2. Studies Included in Systematic Review and Meta-Analysis**

| Study | Miller et al (2020) |
|---|---|
| Barth et al (2016) | ● |
| Cho et al (2019) | ● |
| Thomé et al (2018) | ● |

| Study | Miller et al (2020) |
|---|---|
| Vukas et al (2013) | ● |

**Table 3. Systematic Review and Meta-Analysis Characteristics**

| Study | Dates | Trials | Participants | N (Range) | Design | Duration |
|---|---|---|---|---|---|---|
| Miller et al (2020) | NR-2019 | 4 | Post-discectomy patients with annular defect width of 6-10 mm | 801 (60-554) | Controlled studies (2 RCTs) | ≥2 years |

NR: not reported; RCT: randomized controlled trial.

**Table 4. Systematic Review and Meta-Analysis Results**

| Study | Symptomatic reherniation | Reoperation |
|---|---|---|
| Miller et al (2020) | | |
| Total N | 754 | 797 |
| Pooled effect (95% CI) | Risk ratio, 0.45 (0.31-0.66) | Risk ratio, 0.52 (0.34-0.80) |
| $I^2$ (p) | *0%* (<.0001) | *0%* (.003) |
| Range of N | 60-507 | 60-550 |
| Range of effect sizes (95% CI) | 0.17 (0.02-1.3) to 0.49 (0.33-0.72) | 0.17 (0.02-1.3) to 0.71 (0.20-2.47) |

CI: confidence interval.

### Randomized Controlled Trials

Two key RCTs have evaluated bone-anchored annular closure devices and are summarized in Tables 5 and 6.

Thomé et al (2018) conducted an open-label RCT comparing lumbar discectomy alone or lumbar discectomy with annular closure. A total of 554 patients who had failed nonsurgical treatment and had a disc height of at least 5 mm were randomized. Results at 2 years are summarized in Table 6. Longer follow-up data at 3 years found continued lower risk of reherniation (14.8% vs. 29.5%; p<.001) and reoperation (11% vs. 19.3%; p=.007) in patients receiving an annular closure device (Kienzler et al, 2019). At 5-year follow-up, the risk of symptomatic reherniation (18.8% vs. 31.6%; p<.001) and reoperation (16.0% vs. 22.6%; p=.03) remained lower in patients receiving an annular closure device (Thomé et al, 2021). None of the investigators were blind to treatment assignment, and only patients at specific sites were blind.

Cho et al (2019) published a smaller RCT conducted solely in Korea. Patients were followed for 24 months, and the primary endpoint of the trial was disc height. Patients treated with an annular closure device-maintained disc height at 24 months to a greater extent than those with discectomy alone (86.3% vs. 79.2%; p=.04). Back pain and leg pain were similarly improved in both treatment groups. Recurrent herniation was more common with discectomy alone (Table 6). The small sample size, large loss to follow-up (≤70% at 2-year follow-up), and unclear blinding limit the validity of this trial.

**Table 5. Summary of Key Randomized Controlled Trial Characteristics**

| Study; Trial | Countries | Sites | Dates | Participants | Interventions | |
|---|---|---|---|---|---|---|
| | | | | | Active | Comparator |
| Thomé et al (2018) | EU | 21 | 2010-2014 | Pts 21-75 years of age with single-level disc herniation between L1 andS1, disc height ≥5 mm, and who failed ≥6 weeks of nonsurgical treatment. | Bone-anchored ACD + discectomy (n=276) | Discectomy alone (n=278) |
| Cho et al (2019) | Korea | 1 | NR | Pts with sciatica unresponsive to ≥6 weeks of conservative treatment. | Bone-anchored ACD + discectomy (n=30) | Discectomy alone (n=30) |

ACD: annular closure device; NR: not reported.;

**Table 6. Summary of Key Randomized Controlled Trial Results**

| Study | Recurrent Herniation, % | Clinical Success, %[a] | Reoperation, % | Serious AE, % |
|---|---|---|---|---|
| Thomé et al (2018) | N=507 | N=550 | N=550 | N=550 |
| Annular closure | 50 | 27 | 9 | 7.7 |
| Control | 70 | 18 | 16 | 16.2 |
| MD (95% CI; p-value) | -20% (-12 to -28; p<.001) | 9% (2 to 16; p=.02) | NR (p=.01) | -8.5% (p=.002) |
| NNT (95% CI) | <8 | NR | <13 | NR |
| Cho et al (2019) | N=41 | | | |
| Annular closure | 5 | | | |
| Control | 28.6 | | | |
| Risk (p-value) | NR (p=.044) | | | |

CI: confidence interval; MD: mean difference; NNT: number needed to treat; NR, not reported.
[a] Clinical success was a composite endpoint of Oswestry Disability Index score improvement of ≥15 points, ≥20-point improvement in leg pain on VAS, maintenance of neurologic status, freedom from device- or procedure-related serious adverse events, and freedom from index level reoperation.

The purpose of the study limitations tables (see Tables 7 and 8) is to display notable limitations identified in each study.

**Table 7. Study Relevance Limitations**

| Study | Population[a] | Intervention[b] | Comparator[c] | Outcomes[d] | Duration of Follow-up[e] |
|---|---|---|---|---|---|
| Thomé et al (2018) | 4. Enrolled populations do not reflect relevant diversity | | | | |

| Study | Population[a] | Intervention[b] | Comparator[c] | Outcomes[d] | Duration of Follow-up[e] |
|---|---|---|---|---|---|
| Cho et al (2019) | 4. Enrolled populations do not reflect relevant diversity | | | 1. Study focused on radiologic outcomes | |

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
[a] Population key: 1. Intended use population unclear; 2. Study population is unclear; 3. Study population not representative of intended use; 4, Enrolled populations do not reflect relevant diversity; 5. Other.
[b] Intervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4. Not the intervention of interest (e.g., proposed as an adjunct but not tested as such); 5: Other.
[c] Comparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively; 5. Other.
[d] Outcomes key: 1. Key health outcomes not addressed; 2. Physiologic measures, not validated surrogates; 3. Incomplete reporting of harms; 4. Not establish and validated measurements; 5. Clinically significant difference not prespecified; 6. Clinically significant difference not supported; 7. Other.
[e] Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms; 3. Other.

**Table 8. Study Design and Conduct Limitations**

| Study | Allocation[a] | Blinding[b] | Selective Reporting[c] | Data Completeness[d] | Power[e] | Statistical[f] |
|---|---|---|---|---|---|---|
| Thomé et al (2018) | | 1,2. Participants not randomly allocated | | | | |
| Cho et al (2019) | | 4. Blinding unclear | | 1. High-loss to follow-up or missing data | 1. Power calculations not reported | |

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
[a] Allocation key: 1. Participants not randomly allocated; 2. Allocation not concealed; 3. Allocation concealment unclear; 4. Inadequate control for selection bias; 5. Other.
[b] Blinding key: 1. Participants or study staff not blinded; 2. Outcome assessors not blinded; 3. Outcome assessed by treating physician; 4. Other.
[c] Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication; 4. Other.
[d] Data Completeness key: 1. High loss to follow-up or missing data; 2. Inadequate handling of missing data; 3. High number of crossovers; 4. Inadequate handling of crossovers; 5. Inappropriate exclusions; 6. Not intent to treat analysis (per protocol for noninferiority trials); 7. Other.
[e] Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference; 4. Other.
[f] Statistical key: 1. Analysis is not appropriate for outcome type: (a) continuous; (b) binary; (c) time to event; 2. Analysis is not appropriate for multiple observations per patient; 3. Confidence intervals and/or p values not reported; 4. Comparative treatment effects not calculated; 5. Other.

## Section Summary: Lumbar Discectomy with Annular Closure Devices

For individuals who have lumbar herniated disc(s) and undergo discectomy, use of a bone-anchored annular closure device has been evaluated as a means to reduce reherniation and reoperation in a systematic review and RCTs. The systematic review identified 2 RCTs and 2 nonrandomized trials and found reduced reherniation and reoperation with the addition of the annular closure device to lumbar discectomy. The primary RCT for the bone-anchored annular closure device found reduced reherniation and reoperation at up to 5 years of follow-up, but the trial is limited by lack of blinding.

# SUPPLEMENTAL INFORMATION

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the evidence review conclusions.

## Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

### *International Society for the Advancement of Spine Surgery*

In 2025, the International Society for the Advancement of Spine Surgery (ISASS) published a policy update on the use of bone-anchored annular closure to prevent reherniation in high-risk lumbar discectomy patients. The ISASS update addressees the safety and effectiveness of bone-anchored annular closure devices in individuals undergoing primary discectomy with large annular defects. The ISASS states that bone-anchored annular closure devices may be considered in individuals that present with the following clinical findings:

- "Symptomatic lumbar disc herniation with radiculopathy, confirmed by clinical history, physical examination and imaging
- Single-level disc herniation L4 to L5 or L5 to S1
- Moderately preserved disc height: ≥5 mm posterior height
- Large annular defect (between 4 and 6 mm tall and between 6 and 10 mm wide) visualized intraoperatively after discectomy."

### *North American Spine Society*

In 2014, the North American Spine Society published evidence-based clinical guidelines on the diagnosis and treatment of lumbar disc herniation with radiculopathy. Table 8 summarizes the recommendations specific to open discectomy or microdiscectomy.

**Table 8. Recommendations for Treating Lumbar Disc Herniation With Radiculopathy**

| Recommendations | GOR[a] |
|---|---|
| Endoscopic percutaneous discectomy is suggested for carefully selected patients to reduce early postoperative disability and reduce opioid use compared with open discectomy. | B |
| There is insufficient evidence to make a recommendation for or against the use of automated percutaneous discectomy compared with open discectomy. | I |
| Discectomy is suggested to provide more effective symptom relief than medical/interventional care for patients whose symptoms warrant surgical care. In patients with less severe symptoms, both surgery and medical/interventional care appear to be effective in short and long term relief. | B |
| Use of an operative microscope is suggested to obtain comparable outcomes to open discectomy for patients whose symptoms warrant surgery. | B |
| There is insufficient evidence to make a recommendation for or against the use of tubular discectomy compared with open discectomy. | I |

GOR: grade of recommendation.
[a] Grade B: fair evidence (level II or III studies with consistent findings); grade I: insufficient evidence.

### Ongoing and Unpublished Clinical Trials

Some currently ongoing and unpublished trials that might influence this review can be located at clinicaltrials.gov.

## REFERENCES


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## CODES

To report provider services, use appropriate CPT codes, HCPCS codes, Revenue codes, and/or ICD diagnosis codes.

| Codes | Number | Description |
|---|---|---|
| CPT | 22899 | Unlisted procedure, spine |
| HCPCS | 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 |
| | 63032 | Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc; with repair of annular defect by implantation of bone anchored annular closure device, including all imaging guidance, 1 interspace, lumbar (List separately in addition to code for primary procedure) |
| Type of Service | Surgical | |
| Place of Service | Inpatient | |

## POLICY HISTORY

| Date | Action | Action |
|---|---|---|
| August 2025 | Annual Review | Renewal |
| October 2024 | Annual Review | Policy Renewed |
| October 2023 | New Policy | New Policy Created |

New information or technology that would be relevant for Wellmark to consider when this policy is next reviewed may be submitted to:

Wellmark Blue Cross and Blue Shield
Medical Policy Analyst
PO Box 9232
Des Moines, IA 50306-9232

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