

Local Coverage Determination (LCD): MolDX: Oncotype DX® Genomic Prostate Score for Men with Favorable Intermediate Risk Prostate Cancer (L37305)

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Contractor Information

CONTRACTOR NAME	CONTRACT TYPE	CONTRACT NUMBER	JURISDICTION	STATE(S)
Noridian Healthcare Solutions, LLC	A and B MAC	01111 - MAC A	J - E	California - Entire State
Noridian Healthcare Solutions, LLC	A and B MAC	01112 - MAC B	J - E	California - Northern
Noridian Healthcare Solutions, LLC	A and B MAC	01182 - MAC B	J - E	California - Southern
Noridian Healthcare Solutions, LLC	A and B MAC	01211 - MAC A	J - E	American Samoa Guam Hawaii Northern Mariana Islands
Noridian Healthcare Solutions, LLC	A and B MAC	01212 - MAC B	J - E	American Samoa Guam Hawaii Northern Mariana Islands
Noridian Healthcare Solutions, LLC	A and B MAC	01311 - MAC A	J - E	Nevada
Noridian Healthcare Solutions, LLC	A and B MAC	01312 - MAC B	J - E	Nevada
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LCD Information

Document Information

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L37305

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MoIDX: Oncotype DX® Genomic Prostate Score for Men with Favorable Intermediate Risk Prostate Cancer

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Proposed LCD in Comment Period

N/A

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CMS National Coverage Policy

Title XVIII of the Social Security Act, §1862(a)(1)(A). Allows coverage and payment for only those services that are considered to be reasonable and necessary.

42 Code of Federal Regulations (CFR) 410.32(a). Diagnostic x-ray tests, diagnostic laboratory tests, and other diagnostic tests: Conditions.

Coverage Guidance

Coverage Indications, Limitations, and/or Medical Necessity

This contractor will provide limited coverage for the Oncotype DX[®] Genomic Prostate Score (Genomic Health[®]) (hereafter GPS) to help determine which patients with favorable intermediate-risk, needle biopsy proven prostate cancer, can be conservatively managed rather than treated with definitive surgery or radiation therapy.

Summary of Evidence

In 2016, nearly 181,000 men were diagnosed with prostate cancer in the US which represents 10.7% of all new cancer diagnosis, and prostate cancer accounts for 4.4% of all cancer deaths. Fortunately, 5 year survival for men with prostate cancer is 98.9%.

Many men do not need treatment for their prostate cancer because their prognosis is excellent even without treatment. However, physicians and patients struggle to know who can safely be monitored with active surveillance (AS) versus the subgroup that needs more aggressive treatment to achieve cure, recognizing that definitive treatment for localized prostate cancer can have lifelong morbidities.

Traditionally, clinicopathologic characteristics are utilized to determine risk and subsequent treatment. Risk categories for clinically localized prostate cancer include low-, intermediate-, or high-risk. The majority of men diagnosed with prostate cancer are categorized as low- or intermediate-risk. Within the intermediate-risk group, clinical heterogeneity and variability in prognoses has led to further recognition and subdivision into favorable and unfavorable intermediate-risk.¹

The AUA has recently subcategorized the intermediate-risk group into "favorable" and "unfavorable intermediate-risk group categories. Favorable intermediate-risk are those patients with Grade Group 2 cancers (Grade Group 2 = Gleason 3+4) and PSA<10 ng/ml. Unfavorable intermediate-risk comprised men with either Grade Group 2 cancer with PSA=10-20, or any Grade Group 3 (Grade Group 3 = Gleason 4+3) with PSA<20, and clinical stage cT2b or cT2c.²

Several risk stratification approaches, including those from the NCCN and AUA, have been introduced to try to determine who is at risk of developing metastatic disease and who, if treated early, could avoid this outcome.

NCCN stratifies localized prostate cancer risk on clinical exam, biopsy pathology (Gleason score and number of biopsies positive), PSA and imaging studies.

The NCCN groups are detailed below:

	Risk Category			
	Very Low	Low	Intermediate	High
Clinicopathologic Findings	<ul style="list-style-type: none"> • T1c AND • Gleason score ≤ 6 AND • PSA ≤ 10 ng/mL AND • < 3 prostate cores with tumor AND • $\leq 50\%$ tumor in any core AND • PSA density of < 0.15 ng/mL/g 	<ul style="list-style-type: none"> • T1-T2a AND • Gleason score ≤ 6 AND • PSA ≤ 10 ng/mL 	<ul style="list-style-type: none"> • T2b-T2c OR • Gleason score = 7 OR • PSA 10-20 ng/mL 	<ul style="list-style-type: none"> • T3a OR • Gleason Score 8-10 OR • PSA > 20 ng/mL
Treatment Options				
≥ 20 y life expectancy	<ul style="list-style-type: none"> • Active Surveillance • RT or Brachy • RP (\pm LND) 			
≥ 10 y life expectancy	<ul style="list-style-type: none"> • Active Surveillance 	<ul style="list-style-type: none"> • Active Surveillance • RT or Brachy • RP (\pm LND) 	<ul style="list-style-type: none"> • RP (\pm LND) • RT or Brachy \pm Adj Horm 	<ul style="list-style-type: none"> • RT + Adj Horm • RT + Brachy • RP + LND \pm RT, ADT
< 10 y life expectancy	<ul style="list-style-type: none"> • Observation 	<ul style="list-style-type: none"> • Observation 	<ul style="list-style-type: none"> • RT or Brachy \pm Adj Horm • Observation 	<ul style="list-style-type: none"> • N/A

Table 1: NCCN 2018 V3 - Localized Prostate Cancer Risk Stratification and Treatment

(PSA – Prostate Specific Antigen; RT – Radiation Therapy; RP – Radical Prostatectomy; LND – lymph node dissection; Adj Horm – Adjuvant Androgen Deprivation)

The treatment principles of active surveillance and observation for intermediate risk patients found in the 2018 NCCN guidelines for Prostate Cancer include a recommendation on page PROS-C page 1 of 2 stating that men with “favorable intermediate-risk prostate cancer (predominant Gleason grade 3 [i.e., Gleason score 3+4=7], and percentage of positive biopsy cores < 50 percent, and no more than one NCCN intermediate risk factor) can be considered for active surveillance”. The NCCN also acknowledges that such a choice “should be approached with caution, include informed decision-making, and use close monitoring for progression”.

Use of clinical/pathologic stratification and treatment approaches has led to high cure rates for early stage

prostate cancer. Yet it is widely accepted that many men are over-treated to achieve the cure rate. In the PIVOT trial men with early prostate cancer, initially randomized to radical prostatectomy or observation, showed that over 12 years there was no difference in absolute mortality between the groups. However, this study was hampered by several problems including:

- Only 731 of 5023 eligible patients chose to participate in the study based on randomization criteria.
- In the group randomized to RP: only 85% of the men received definitive therapy (79% surgery; 6% other).
- In the observational group: 10% of the observation group received RP initially and additional 20% eventual received definitive treatment. Despite broad inclusion criteria, > 50% of patients had a PSA of <10 (median PSA of 7) and had biopsy proven T1c disease.
- Although there were a significant number of patients with Gleason score ≥ 7 (25%), 40% of men were classified initially as being low risk; and 30% were intermediate.

Although subgroups were small, it appears that high-risk groups (including those with PSA > 10) benefitted from RP. Furthermore, there was a trend for the intermediate risk patients to benefit from RP as well. The small number of patients willing to enter the study, and the high rate of crossover (both initially and subsequently) demonstrates the difficulty of doing observation trials in the United States.

Recent reports on prostate cancer diagnosis and management in the United States evaluated data from the US National Cancer Data Base and the Cancer of the Prostate Strategic Urologic Research Endeavor (CaPSURE) to summarize the use of various treatments, including changes over time. Although the use of active surveillance for men with low-risk prostate cancer increased over time, it was utilized in only 18.4 - 40% of patients despite societal guidelines supporting its use in this population. In the intermediate-risk group, active surveillance was pursued in only 4-8% of patients. The availability of molecular diagnostic tests that provide a more accurate prediction of oncologic endpoints like adverse pathology, biochemical recurrence, the development of metastases, and 10-year disease specific mortality, compared to standard clinical and pathologic features, provides an opportunity to identify men who may safely pursue active surveillance and increase physician/patient confidence in that choice. The benefits associated with active surveillance and foregoing immediate intervention for appropriate men include a reduction in treatment related complications and avoidance of adverse events like erectile dysfunction, urinary incontinence, bowel dysfunction, and depression.

Oncotype DX® Genomic Prostate Score (GPS)

Test Description

Oncotype DX® GPS is a prostate biopsy-based 17 gene RT-PCR assay, representing four molecular pathways (androgen signaling, cellular organization, stromal response, and proliferation), that provides a biologic measure of cancer aggressiveness. The assay identifies men who are considered candidates for active surveillance, including those with NCCN very low, low and favorable intermediate risk disease*. The assay is designed to inform decisions between AS and immediate treatment.

**NCCN Guidelines state that men with favorable intermediate-risk prostate cancer may be considered for active surveillance.*

Test Performance

Three validation studies demonstrate:

- In men with NCCN very low-, low-, or intermediate-risk prostate cancer who were potential candidates for AS, the GPS was prospectively validated as a biopsy-based predictor of adverse pathology (AP)^{3, 4}, biochemical recurrence (BCR)^{4, 5}, metastasis⁶, thus establishing the assay as a robust and independent measure of

prostate cancer aggressiveness.

- The GPS adds independent information beyond standard clinical and pathologic measures and assesses underlying biology from very small biopsy tumor volumes, while also addressing issues of tumor heterogeneity and biopsy under-sampling, to predict disease aggressiveness.
- Men with NCCN very low-, low-, or intermediate-risk prostate cancer and a GPS of ≤ 20 have a very low risk of developing metastasis and/or prostate cancer specific death at 10 years.
- The incorporation of the GPS to current clinical stratification enables identification of a larger population of patients who may more confidently choose AS or immediate therapy as an initial management strategy.

Clinical Validation for Adverse Pathology (AP)³

A prospective-retrospective clinical validation of the Oncotype DX® Genomic Prostate Score assay was conducted in a contemporary cohort of 395 prostate cancer patients with NCCN very low-, low-, or intermediate-risk disease (GS3+4 in ≤ 2 cores and $< 33\%$ positive) who were considered candidates for AS based on histologic criteria but who had opted to have radical prostatectomy at the University of California San Francisco from 1997 to 2011.² The objectives were to validate the GPS as a predictor of AP at radical prostatectomy, a hallmark of aggressive disease, and to determine whether the GPS added independent predictive information beyond standard clinical and pathologic data.

The assay was successfully performed in 96% of needle biopsy specimens; 99.5% of samples with ≥ 10 ng/ml RNA yielded a GPS result. Per the pre-specified primary analysis, the GPS was a significant predictor of RP pathology across all patients tested ($p=0.002$). In post-hoc analysis, GPS was also a significant predictor of RP pathology for the sub-set of patients with NCCN favorable intermediate risk disease ($p<0.001$). While conventional clinical risk assessment tools stratified risk, the incorporation of the GPS identified the wide range of biologic risk within each conventional (NCCN and CAPRA) risk group. In multivariable analysis, the GPS was found to predict AP at radical prostatectomy, even after accounting for several standard clinical risk factors (biopsy GS, clinical T-stage, baseline PSA, and age). Further analyses showed that by incorporating the GPS results with previously defined clinical risk assessment tools such as NCCN or CAPRA, more patients were identified with very low- and low-risk biologic potential and, as appropriate candidates for AS. Together, the GPS and the NCCN risk group provide a more accurate prediction of AP (reported as the likelihood of favorable pathology or 1 - likelihood of AP), at the time of diagnosis to help guide individual treatment decisions.

Clinical Validation for Adverse Pathology (AP) and Biochemical Recurrence (BCR)⁴

For the second validation study, a large cohort with a high proportion of African-American men (20%) in the Center for Prostate Disease Research (CPDR) multi-center longitudinal data base was identified to test the association of GPS with tumor aggressiveness, as measured by three endpoints: (1) AP at surgery (immediately actionable), (2) BCR and (3) metastasis.⁴ This prospective-retrospective clinical validation study included 402 men with NCCN very low-, low- and intermediate-risk prostate cancer treated with radical prostatectomy between 1990-2011 at two US military medical centers (Walter Reed National Military Medical Center and Madigan Army Medical Center).

In pre-planned, univariable analyses, GPS was validated as a significant predictor of BCR (primary objective) and confirmed as a significant predictor of AP (first secondary objective) after adjustment for biopsy GS. In addition, while there were very few metastatic events in this low- to intermediate-risk population ($n=5$ events), there was a strong association of GPS with metastatic recurrence. In multivariable analyses, GPS continued to be strongly associated with BCR and AP after adjustment for NCCN risk group, indicating that GPS adds value beyond standard clinicopathologic features. A broad and overlapping range of

GPS values was observed within each NCCN risk group, age quartile, and racial group. Importantly, GPS distribution, median values, and association of GPS with aggressive prostate cancer outcomes were similar between African-American and Caucasian men.

Both validation studies were designed in a similar fashion, using the same definition of AP and centralized pathology review. Importantly, the second validation study was conducted in a broader population, and there was a pre-planned analysis of 337 of the 402 men that had clinical and pathological characteristics matching the entry criteria of the first validation study (biopsy GS 3+3 and low volume [≤ 3 or $\leq 33\%$ positive cores] GS 3+4). In this group, GPS was again strongly and significantly associated with AP after adjustment for clinical and pathologic factors, and was predictive of both high-grade and non-organ-confined disease after adjusting for biopsy Gleason score (GS), and after adjustment for significant factors from the univariable analysis (including age and NCCN risk group). In additional post hoc analysis focused on NCCN Favorable Intermediate risk patients, there was a trend to significance ($p=0.076$) for the prediction of adverse pathology. When the Clinical Validation Studies #1 and #2 are combined, in the 275 patients with favorable intermediate risk disease, the HR for risk of adverse pathology per 20 unit increase in GPS was 2.9 (95% C.I. 1.7-5.1) ($P<0.001$).

Clinical Validation for the Development of Metastasis and Prostate Cancer Specific Death^{5, 6}

To determine if the GPS result was strongly associated with the development of metastasis and prostate cancer specific death, we collaborated with an integrated healthcare system. Using a longitudinal cohort of 6,184 men with prostate cancer, all treated within their health care system, we performed a prospective-retrospective stratified sampling designed study that included all men who experienced prostate cancer specific mortality. The final study population consisted of 279 patients treated with radical prostatectomy that experienced 64 prostate cancer specific death (PCD) events and 79 metastatic events.

Valid GPS results were obtained for 259 men (93%). In univariable analysis, GPS was strongly associated with prostate cancer-specific death (PCD) (HR/20 GPS units = 3.23 ($p < 0.001$)) and metastasis (HR/20 units=2.75 ($p < 0.001$)). The association between GPS and both endpoints remained significant in multivariable analysis after adjusting for NCCN: 1) PCD: HR/20 units = 2.69; 2) metastasis: HR/20 units=2.34 ($p<0.001$ for each). The GPS was also significantly associated with both endpoints adjusting for AUA and CAPRA risk groups with similar hazard ratios ($p<0.001$ for each). No patients with low- or intermediate-risk disease and a GPS result ≤ 20 developed metastases or PCD.

The striking result of having no PCD or metastatic events for men with NCCN very low-, low-, or intermediate-risk prostate cancer and a GPS score of ≤ 20 caused evaluation of this GPS value as a potential cut point. Upon further review, a strong association for this cut point and the development of metastasis and PCD was identified. For all risk groups, the overall risk for PCD within 10 years for men who had prostate cancer with a GPS of < 20 was 0.7% versus 2.7% for those with a GPS > 20 . For all risk groups, the overall risk for developing clinical recurrence (metastasis or local recurrence) within 10 years for men who had prostate cancer with a GPS of < 20 was 2.4% versus 9.1% for those with a GPS > 20 . An evaluation of the combined development study ($n=426$) and the CPDR study ($n=402$) yielded a total number of 39 PCD events and 114 clinical recurrences (metastatic and local recurrences). There was only one PCD that occurred in a man with NCCN low risk prostate cancer who had a GPS < 20 .

Criteria for Coverage

Oncotype DX® Genomic Prostate Score test is covered for men with favorable intermediate risk prostate

cancer only when the following clinical conditions are met:

- Needle biopsy with localized adenocarcinoma of prostate (no clinical evidence of metastasis or lymph node involvement), and
- FFPE prostate biopsy specimen with at least 0.5 mm of cancer length, and NCCN Favorable Intermediate-risk disease defined as:
 - Gleason Grade Group 2 (Gleason Sum 3+4=7), and
- Patient has an estimated life expectancy of greater than or equal to 10 years, and
- Patient is a candidate for and is considering conservative therapy and yet would be eligible for definitive therapy (radical prostatectomy, radiation therapy or brachytherapy), and
- Result will be used to determine treatment between definitive therapy and conservative management, and
- Patient has not received pelvic radiation or androgen deprivation therapy prior to the biopsy, and Patient is monitored for disease progression according to established standard of care.

Analysis of Evidence (Rationale for Determination)

Level of Evidence:

Quality – Moderate

Strength – Limited

Weight – Limited

This contractor recognizes that the evidence of clinical utility for the use of GPS test for patients with favorable intermediate risk, needle biopsy proven prostate cancer that can be conservatively managed rather than treated with definitive surgery or radiation therapy is promising at the current time. However, this contractor believes that forthcoming prospective clinical studies and analysis in these patients will demonstrate the use of active surveillance (AS) in GPS-tested favorable intermediate-risk patients will demonstrate improved patient outcomes. Continued coverage for GPS testing is dependent on annual review by this contractor of prospectively derived scientific data and publications that demonstrate enhanced clinical utility for the GPS test.

Data collected by Genomic Health® through studies currently underway and/or tested patients will support utility including:

- Data collected for all Oncotype DX GPS tested patients at the time of test requisition:
 - Prostate Specific Antigen (PSA) ng/mL
 - Gleason Sum (i.e. 3+4=7)
 - Clinical Stage
- Data generated to demonstrate that men with Favorable Intermediate risk cancer and a GPS ≤ 20 are not at high risk of definitive treatment during monitoring for disease progression
 - Within this group of patients, the rate of definitive treatment intervention is expected to be $<20\%$.
 - In the absence of a universally accepted timeframe for repeat biopsies within existing AS recommendations, men should be monitored for disease progression per NCCN guidelines v3.2016 “Principles of Active Surveillance”, with the expectation of a repeat biopsy preferably by 12 months but no later than 18 months of enrollment.
 - For each patient who pursues definitive treatment (after initially pursuing AS), the time on active surveillance and the reason for intervention will be collected, including:

- Number of positive number of biopsies and maximum Gleason score on subsequent biopsy and pathology report
- For patients who choose radical prostatectomy, the pathology report from the surgical specimen will be recorded
- Imaging suggestive of disease progression (Response Evaluation Criteria in Solid Tumors; RECIST)
- Patient choice in absence of the above
- Among the group of patients described above, those who proceed to definitive treatment will not be at a >20% risk of disease progression, as defined by biochemical recurrence, metastases, or DSM.
- Toward further demonstration of clinical utility, additional data collected will include
 - The rate of AS, and
 - Subsequent definitive treatment intervention, and
 - Risk of disease progression among contemporaneous men with favorable intermediate risk prostate cancer who do NOT receive a GPS.

This additional data is expected to firmly establish clinical utility by identifying men with intermediate risk prostate cancer with a low GPS who can be comfortable with AS and avoid unnecessary procedures and/or interventions.

General Information

Associated Information

N/A

Sources of Information

N/A

Bibliography

1. NCCN Clinical Practice Guidelines in Oncology: Prostate Cancer, v3.2018.
2. Sanda MG, Chen RC, Crispino T, et al. Clinically localized prostate cancer: AUA/ASTRO/SUO Guideline. AU, 2017. [http://www.auanet.org/guidelines/clinically-localized-prostate-cancer-new-\(aua/astro/suo-guideline-2017\)](http://www.auanet.org/guidelines/clinically-localized-prostate-cancer-new-(aua/astro/suo-guideline-2017))
3. Klein EA, Cooperberg MR, Magi-Galuzzi C, et al. A 17-gene assay to predict prostate cancer aggressiveness in the context of Gleason grade heterogeneity, tumor multifocality, and biopsy undersampling. *Eur Urol.* 2014;66:1: 550-60.
4. Cullen J, Rosner IL, Brand TC, et al. A biopsy-based 17-gene genomic prostate score predicts recurrence after radical prostatectomy and adverse surgical pathology in a racially diverse population of men with clinically low- and intermediate-risk prostate cancer. *Eur Urol.* 2014;68(1):123-31.
5. Validation of a 17-Gene Genomic Prostate Score as a predictor of biochemical recurrence in men with prostate cancer treated with radical prostatectomy in a community setting. Accepted for presentation at the annual ASCO Genitourinary Cancer Symposium, February 2017.
6. Clinical validation of a 17-Gene Genomic Prostate Score assay as a predictor of distant metastases in men with prostate cancer treated with radical prostatectomy in a community setting. Accepted for presentation at the annual European Association of Urology annual meeting, March 2017.

Revision History Information

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASON(S) FOR CHANGE
11/01/2019	R6	<p>The LCD is revised to remove CPT/HCPCS codes in the Keyword Section of the LCD.</p> <p>At this time 21st Century Cures Act will apply to new and revised LCDs that restrict coverage which requires comment and notice. This revision is not a restriction to the coverage determination; and, therefore not all the fields included on the LCD are applicable as noted in this policy.</p>	<ul style="list-style-type: none"> Other (The LCD is revised to remove CPT/HCPCS codes in the Keyword Section of the LCD.)
11/01/2019	R5	<p>CMS references were revised.</p> <p>At this time 21st Century Cures Act will apply to new and revised LCDs that restrict coverage which requires comment and notice. This revision is not a restriction to the coverage determination; and, therefore not all the fields included on the LCD are applicable as noted in this policy.</p>	<ul style="list-style-type: none"> Creation of Uniform LCDs With Other MAC Jurisdiction
11/01/2019	R4	<p>As required by CR 10901, all billing and coding information has been moved to the companion article, this article is linked to the LCD.</p> <p>At this time 21st Century Cures Act will apply to new and revised LCDs that restrict coverage which requires comment and notice. This revision is not a restriction to the coverage determination; and, therefore not all the fields included on the LCD are applicable as noted in this policy.</p>	<ul style="list-style-type: none"> Revisions Due To Code Removal
01/01/2019	R3	<p>The LCD is revised to replace CPT 81479 with 0047U effective 1/1/2019.</p> <p>This paragraph, "The AUA has recently subcategorized the intermediate-risk group into "favorable" and "unfavorable intermediate-risk group categories. Favorable intermediate-risk are those patients with Grade Group 2 cancers (Grade Group 2 = Gleason 3+4) and PSA<10 ng/ml. Unfavorable intermediate-risk comprised men with either Grade Group 2 cancer with PSA=10-20, or any Grade Group 3 (Grade Group 3 = Gleason 4+3) with PSA<20, and clinical stage cT2b or cT2c.2" added with an effective date of 3/18/18.</p>	<ul style="list-style-type: none"> Revisions Due To CPT/HCPCS Code Changes

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASON(S) FOR CHANGE
08/16/2018	R2	Revised the last three (3) paragraphs above the table and made minor revisions to update the NCCN reference to the 2018 version under Table: 1.	<ul style="list-style-type: none"> • Creation of Uniform LCDs With Other MAC Jurisdiction
03/18/2018	R1	Removed bibliography entry #7 and all content related to it.	<ul style="list-style-type: none"> • Creation of Uniform LCDs With Other MAC Jurisdiction

Associated Documents

Attachments

N/A

Related Local Coverage Documents

Article(s)

A56371 - Billing and Coding: MoIDX: Genomic Health™ Oncotype DX® Prostate Cancer Assay

A55839 - Response to Comments: MoIDX: Oncotype DX® Genomic Prostate Score for Men with Favorable Intermediate Risk Prostate Cancer

LCD(s)

DL37305

- (MCD Archive Site)

Related National Coverage Documents

N/A

Public Version(s)

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Updated on 03/29/2019 with effective dates 01/01/2019 - 10/31/2019

Some older versions have been archived. Please visit the MCD Archive Site to retrieve them.

Keywords

N/A