Department of Health and Human Services
[LOGO] **OFFICE OF MEDICARE HEARINGS AND APPEALS**
Miami, Florida

Appeal of: **AGENDIA INC**	OMHA Appeal No.: **1-2376151948**
Beneficiary: **Multiple (See Attachment A)**	Medicare: **Part B**
Medicare No.: **Multiple (See Attachment A)**	Before: **Scott Tews** Administrative Law Judge

DECISION

After considering the evidence and arguments presented in the record, I enter an **UNFAVORABLE** decision. The tests furnished to the various beneficiaries on various dates of service are not medically reasonable and necessary and are not covered by Medicare. The provider is responsible for the non-covered costs.

PROCEDURAL HISTORY

The Appellant filed claims with Palmetto GBA (later changed to Noridian Healthcare Solutions) (collectively referred to as the "Medicare Administrative Contractor-) for molecular diagnostic services rendered to multiple beneficiaries on various dates of service. *See* Attachment A. The Medicare Administrative Contractor denied payment on initial determination

and redetermination. (Exhibit 2). The Appellant requested a reconsideration. (Exhibit 1).

C2C Solutions, Inc., the Qualified Independent Contractor (the "QIC"), issued an unfavorable reconsideration. (Exhibit 1). The QIC found that the Appellant was liable for the denied charges. The Appellant requested a hearing before an Administrative Law Judge. (Exhibit 3).

A telephone hearing was held on March 7, 2019. Patric Hooper, Esq., of the law firm Hooper, Lundy & Bookman, PC, represented the Appellant. Testifying under oath on behalf of the Appellant were Dr. William Audeh, Oncologist and Chief Medical Officer and Bas Van der Baan, Chief Clinical Officer. Exhibits 1-5 were admitted into the record without objection.

ISSUE(S)

The issues to be determined by the Administrative Law Judge (ALJ) are:

Can Medicare payment be allowed under Title XVIII of the Social Security Act (the "Act") for the molecular diagnostic services performed by the Appellant on multiple beneficiaries on various dates of service, as listed on Attachment A?

If the services are found to be not reasonable and necessary, do the limitation of liability provisions under Section 1879 of Title XVIII of the Act apply, and, if so, to whom?

APPLICABLE LAW AND POLICY

I. Principles of Law

A. Statutes and Regulations

The Supplementary Medical Insurance program (Part B of Title XVIII of the Act) provides coverage for a variety of medical and other health services furnished by physicians and for a number of other specific health-related items and services. Act § 1832(a); see also 42 C.F.R. § 410.3. Individuals participate voluntarily in the Medicare Part B program and pay a monthly premium. Act § 1831; *see also* 42 C.F.R. § 407.2.

Section 1832(a)(1) of the Act permits payment for "medical and other health services" as a Medicare Part B benefit, including "physician services" and "diagnostic tests." Physician services include diagnosis, therapy, surgery, consultations and home, office and institution calls. 42 C.F.R. § 410.20.

Section 1833 of the Act states that no payment can be made to the provider or another person unless such information, as may be necessary, has been furnished in support of the medical necessity of the claimed services in order to determine the amount due such provider or other individual.

Section 1862(a)(1)(A) of the Act states that no Medicare payment can be allowed for items or services which are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.

When Medicare coverage is precluded under Section 1862(a)(1)(A) of the Act, i.e., the item was not reasonable and necessary, payment will be made, notwithstanding the preclusion, when neither the individual who received the item nor the person who furnished the item knew or could reasonably be expected to know that the item was not covered, pursuant to the limitation of liability provision found in Section 1879 of the Act.

Pursuant to 42 C.F.R. § 410.32, all diagnostic x-ray, diagnostic laboratory tests, and other diagnostic tests must be ordered by the physician who is treating the beneficiary, that is, the physician who furnishes a consultation or treats a beneficiary for a specific medical problem and who uses the results in the management of the beneficiary's specific medical problem. Tests not ordered by the physician who is treating the beneficiary are not reasonable and necessary. 42 C.F.R. § 410.32(a).

A. Policy and Guidance

Section 1871(a)(2) of the Act states that no rule, requirement, or statement of policy (other than a national coverage determination) that establishes or changes a substantive legal standard governing the scope of benefits, the payment for services, or the eligibility of individuals, entities, or organizations to furnish or receive services or benefits under this title shall take effect unless it is promulgated by the Secretary by regulation. However, in lieu of binding regulations

with the full force and effect of law, the Centers for Medicare and Medicaid Services (CMS) and its contractors have issued policy guidance describing the criteria for coverage of selected items and services in the form of manuals and local coverage determinations (LCDs), respectively.

A service is "diagnostic" if it is an examination or procedure to which the patient is subjected, or which is performed on materials derived from the patient, to obtain information to aid in the assessment of a medical condition or the identification of a disease. Among these examinations and tests are diagnostic laboratory services such as hematology and chemistry, diagnostic x-rays, isotope studies, EKGs, pulmonary function studies, thyroid function tests, psychological tests, and other tests given to determine the nature and severity of an ailment or injury. CMS, *Medicare Benefit Policy Manual (MBPM) (Internet Only Manual Publ'n 100-2)*, ch. 6, § 20.4.1 (2008).

The Medicare Administrative Contractor has issued an LCD relating to molecular diagnostic services. Palmetto GBA, Local Coverage Determination L32288: Molecular Diagnostic Tests (MDT) (LCD L32288) (orig. det. eff. date May 2012) (rev. eff. date Sept. 2012) (rev, ending date April 2013) (now superseded). It states, in relevant part, the following:

Indications and Limitations of Coverage and/or Medical Necessity

This policy confirms 'non-coverage' for all molecular diagnostic tests (MDT) that are not explicitly covered by a National Coverage Determination (NCD), a Local Coverage Determination (LCD), a coverage article published by Palmetto GBA and excluded per MolDx Exempt Tests published on the Palmetto GBA website.

MDT Policy Specific Definitions

1. **MDT:** Any test that involves the detection or identification of nucleic acid(s) (DNA/RNA), proteins, chromosomes, enzymes, cancer chemotherapy sensitivity and/or metabolite(s). The test may or may not include multiple components. Molecular Diagnostic Tests (MDT) https://localcoverage.cms.gov/mcd_archive/view/lcd.aspx?lcdInfo=32288%3a12. A MDT may consist of a single mutation analysis/identification, and/or may or may not rely upon an algorithm or other form of data evaluation/derivation.
2. **LDT:** Any test developed by a laboratory developed without FDA approval or clearance.

Applicable Tests/Assays

In addition to the MDT definition, this non-coverage policy applies to all tests that meet at least one of the following descriptions:

1. All non-FDA approved/cleared laboratory developed tests (LDT)

2. All modified FDA-approved/cleared kits/tests/assays
3. All tests/assays billed with more than one CPT code to identify the service, including combinations of method based, serology-based, and anatomic pathology codes
4. Billed with an NOC code

Unique Test Identifier Requirement

Because the available language in the HCPCS and CPT manuals to describe the pathology and laboratory categories and the tests included in those categories are not specific to the actual test results provided, all MDT services must include an identifier as additional claim documentation. Test providers must apply for an identifier specific to the applicable test and submit the test assigned identifier with the claim for reimbursement. The assigned identifier will provide a crosswalk between the test's associated detail information on file and the submitted claim detail line(s) required to adjudicate each test's claim. The unique identifier limits the need to submit the required additional information about the test on each claim.

Since CMS has not recognized CPT codes for payment, all MDT described by CPT codes must also obtain unique identifiers.

Laboratory providers who bill MDT services must register services with one of the following methods:

Z-Code Identifier Application

Palmetto GBA Test Identifier (PTT) Application

Technology Assessments (TA)
Palmetto GBA must review all test/assay clinical information to determine if a test meets Medicare's reasonable and necessary requirement. Labs must submit a comprehensive dossier on each new test/assay prior to claim submission. Palmetto GBA will only cover and reimburse tests that demonstrate analytical and clinical validity, and clinical utility. Prior to this tech assessment and published coverage determination, Palmetto will consider all tests investigational and therefore, not a covered service. The coverage effective date and the publication date will be the same.

Payment Rules
Palmetto GBA will apply the following payment rules:
Tests submitted and paid that have NOT been reviewed and approved through the process outlined in this policy will be considered investigational and therefore denied as not a covered service.
Approved tests will be effective for dates of service on and after the approval date of a coverage determination.
Dates of service prior to the approval effective date are subject to this non-coverage policy.

Non-covered Tests
The following test types are not considered a Medicare benefit and therefore will be denied:

Tests considered screening in the absence of clinical signs and symptoms of disease

> Tests that do not provide the clinician with actionable data (information that will improve patient outcomes and/or change physician care and treatment of the patient)
> Tests that confirm a diagnosis or known information
> Tests to determine risk for developing a disease or condition
> Tests without diagnosis specific indications
> Tests performed to measure the quality of a process
> Tests for Quality Control/Quality Assurance (QA/QC), i.e. tests performed to ensure a tissue specimen matches the patient

Section 1879 of the Act provides in pertinent part that the liability of the beneficiary and/or provider of services may be waived in cases where payment is not made by reason of sections 1862(a)(1) or (9), if the beneficiary or provider did not know or could not be reasonably expected to have known that the care was not covered.

FINDINGS OF FACT AND ANALYSIS

The following facts are established by a preponderance of the evidence:

1. All of the beneficiaries at issue in this appeal were diagnosed and treated for early-stage breast cancer (malignant neoplasm of the female breast, ICD-9 codes 174.1-174.9). This appeal involves claims for 153 beneficiaries.
2. All services at issue were provided as billed and ordered by a physician. The two types of

tests that were provided are known as (1) the BluePrint assay (CPT 84999, identifier PB841); and (2) TargetPrint array-based evaluation (CPT 88386, identifier PB840). Also included in the appeal are claims for an unlisted molecular pathology code (CPT 84179) and microdissection (CPT 88381), an ancillary service to the molecular diagnostic testing at issue.

3. Mr. Van der Baan gave background information concerning Agendia Inc. and the state of genetic research since the acceleration of genetic technology since 2000. Mr. Van der Baan mentioned that one of the early genomic tests, MammaPrint, which analyzes the activity of certain genes in early-stage breast cancer, is paid by Medicare. According to Mr. Van der Baan, the BluePrint and TargetPrint tests were developed to more accurately address the receptor status in order to provide the best treatment options for the cancer patient. Mr. Van der Baan stated that these tests have been accepted as the standard of care in the medical community, and there was published evidence-based articles in effect during the dates of service at issue, which show that BluePrint and TargetPrint are more accurate than conventional pathology methods in determining the receptor status and response to treatment in early-stage breast cancer patients.
4. Dr. Audeh explained that prior to the growth of genetic technology, the medical community was aware that there were 3 types of breast cancer, all of which were treated with chemotherapy. With the growth in genetic technology,

tests were developed to be more precise in identifying the type or classification of the individual's cancer, and accordingly, more precise in how to effectively treat the type of cancer in that individual. Dr. Audeh noted that prior to the development of the genetic testing, there was a 1 in 5 error rate in correctly identifying the type of cancer, and it appeared that the imperfections in accurately identifying the type of cancer was the result of the timing or handling between the surgeon and the pathologist of the cells for biopsy. Dr. Audeh noted that in contrast, with genetic tests, there is more precision in the classification of the cancer cells, which leads to more precise treatment options and better results for the cancer patient. Dr. Audeh explained that BluePrint classifies the three types of cancer cells: 1) cells that are hormone driven (luminal); 2) cells that are HER2 (human epidermal growth factor receptor driven); and 3) cells that are basal, and which can be treated by chemotherapy only. Dr. Audeh stated that the TargetPrint test looks at the 3 types of receptor genes: 1) estrogen receptor gene; 2) progesterone receptor gene; and 3) HER2 gene. He stated that in each case, these tests are not affected by the way the cells are handled by the pathologist. Dr. Audeh explained that the tests yield different information in that TargetPrint shows how positive a single gene is, whereas, BluePrint gives different information with respect to a pathway analysis. Dr. Audeh noted that in 2012, both these tests were in conjunction, and the

physician used both results to plan the patient's course of treatment. Dr. Audeh summarized that the standard pathology reports have a lot of gray zones, whereas, the BluePrint and TargetPrint tests are more precise and supplement the pathologist report in order to better decide the course of treatment. Dr. Audeh stated that by 2012, the use of these tests were the standard of care for oncologists.

Dr. Audeh proceeded to explain how these tests worked in 5 of the beneficiary cases in terms of identifying the type of cancer and in making decisions on the treatment of breast cancer:

(a) *E.M.*

This beneficiary was diagnosed with Stage 2 breast cancer. Pathology showed she had an estrogen positive cancer that was also negative for progesterone. The TargetPrint test confirmed she was estrogen positive and progesterone positive. The BluePrint test showed that she had a hormone-driven cancer. Based on these tests it was determined that hormone treatment was probably not enough, and that she would also need chemotherapy.

(b) *J.M.*

This beneficiary was diagnosed with a relatively small (less than 1 cm) Grade 2 breast cancer. Pathology showed it may be a high-risk cancer, and that she had an estrogen positive cancer that was also negative for progesterone and a HER2 negative result. However,

the genomic information revealed that she was low risk and did not require chemotherapy. The BluePrint test revealed a strongly hormone-driven cancer that can be treated with hormone treatments alone. The TargetPrint test confirmed the showing of estrogen positive.

(c) *R.M.*

This beneficiary was diagnosed with a Stage 1 breast cancer (upper limits of Stage 1 with a tumor over 2 cm in size). Pathology found it to be an estrogen positive, Grade 2 cancer. Pathology was uncertain as to risk and whether hormone treatment alone would be adequate or if she would need chemotherapy. The BluePrint test showed the beneficiary had an estrogen negative cancer that was genomically not hormone driven. The BluePrint test revealed a basal breast cancer, which is an extremely aggressive cancer but very sensitive to chemotherapy. This also showed that the beneficiary could be treated with aggressive chemotherapy before surgery to reduce the size of the tumor. Without chemotherapy, the tumor probably would have metastasized rapidly.

(d) *J.G.*

This beneficiary was diagnosed with more advanced Stage 2 breast cancer with evidence of the cancer having also spread to her lymph nodes under her arm. Pathology indicated that it was an estrogen positive cancer and suggested a very likely need for chemotherapy.

> The BluePrint test revealed a basal breast cancer and gave no indication that anti-estrogen treatment alone would be beneficial. The genomic information directed the beneficiary towards the most curative form of treatment.
>
> (e) *S.C.*
>
> This beneficiary was diagnosed with a large cancer in her breast – Stage 2 or 3 locally advanced cancer. Pathology found it was an estrogen positive, Grade 2 cancer. There was a significant treatment question if she should receive chemotherapy and the large size tumor may be difficult to surgically remove. The BluePrint test revealed a basal breast cancer. The TigerPrint test confirmed an estrogen negative cancer. The genomic information revealed that the beneficiary was high risk and in need of chemotherapy. Preoperative chemotherapy would be highly successful to shrink the tumor size for surgical removal.
>
> Dr. Audeh testified that these five (5) excerpted cases are representative of all of the other beneficiaries' claims in this appeal. *(Hearing Recording).*

Upon careful consideration of the record, CMS's memorandum, and the appellant's exceptions, the undersigned finds that the services at issue are not covered by Medicare. The record demonstrates that both tests, the BluePrint and TargetPrint, were reviewed by the MolDx program, and neither had sufficient evidence to

support the reasonable and necessary criteria for Medicare reimbursement.

The purpose of the MolDx program is specifically to analyze and review the analytical validity, clinical validity, and clinical utility of molecular diagnostic tests. The assessment and review process under the MolDx program is specialized for molecular diagnostic tests, considers applicable statutory and regulatory requirements, and includes the review of scientific literature by independent subject matter experts.

For the BluePrint test, Policy Article A51931 specifically states that Palmetto GBA has completed a technical assessment on this test, and to date, there is insufficient evidence to support reasonable and necessary criteria for Medicare reimbursement. LCD L32288 states, prior to the technical assessment and published coverage determination, Palmetto will consider all tests investigational and therefore, not a covered service.

While there is no specific policy article that addresses the TargetPrint test, it is clear from Palmetto GBA's redeterminations that this test also was reviewed by the MolDx program, and also found to not have sufficient evidence to support the reasonable and necessary criteria for Medicare reimbursement. The appellant would have submitted all of the clinical studies available at the time of the technical assessment with its application. *See* MolDx Manual, Ch. 2, § 2.2. While the appellant's expert, who is the appellant's Chief Medical Officer, opined that the tests are medically

reasonable and necessary, and met Medicare's coverage criteria for MDTs, the technical assessment performed under the MolDx program determined otherwise.

In accordance with the LCD and policy article, the undersigned concludes that, based upon a preponderance of the evidence, both the BluePrint or TargetPrint tests are not covered by Medicare.

When an item or service is denied as not medically "reasonable and necessary" under § 1862(a)(1)(A) of the Act, § 1879 of the Act limits the liability of a beneficiary or supplier that did not know, and could not reasonably have been expected to know, that the item or service would not be covered by Medicare. A beneficiary is considered to have "knowledge" of non-coverage if the supplier provides advance written not ice to the beneficiary explaining why it believes that Medicare will not cover the items. 42 C.F.R. § 411.404(b). In this case, there is no evidence in the record that any of the respective beneficiaries were provided with advance written notice of non-coverage.

In contrast, a provider or supplier has actual or constructive knowledge of non-coverage based upon its receipt of CMS notices, manual issuances, bulletins, and other written guides or directives and its knowledge of acceptable standards of practice by the local medical community. *See* 42 C.F.R. § 411.406(e). It is clear from the record that the appellant was aware of the applicable authorities, as the appellant submitted applications

for these tests to be reviewed by the MolDx program. The appellant would have received direct notice of the coverage determinations for these tests. *See also* Palmetto GBA, MolDx Excluded Tests, available at https://www.palmettogba.com/palmetto/MolDx.nsf/docsCat/MolDx%20Website~Browse%20By%20Topic~Excluded%20Tests. In addition, as a Medicare supplier, the appellant is also deemed to have had constructive notice of the coverage criteria (including LCDs and Policy Articles) of the tests for which it submitted Medicare claims.

For these reasons, the undersigned finds the appellant knew, or could have reasonably been expected to know, that Medicare would not cover the BluePrint and TargetPrint tests, and related services, at issue here. Accordingly, the undersigned concludes the appellant if financially responsible for the non-covered costs.

CONCLUSIONS OF LAW

Medicare payment cannot be made for the molecular diagnostic testing at issue, as detailed on Attachment A to this decision.

ORDER

For the reasons discussed above, this decision is **UNFAVORABLE**. The provider is responsible for the non-covered costs. I direct the Medicare Administrative

Contractor to process the claim in accordance with this decision.

SO ORDERED

Scott A. Tews –S

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Scott Tews
Administrative Law Judge