PLA 0155U: Oncology (breast cancer), DNA, PIK3CA (phosphatidylinositol-4,5-bisphosphate 3- kinase, catalytic subunit alpha) (eg, breast cancer) gene analysis (ie, p.C420R, p.E542K, p.E545A, p.E545D [g.1635G>T only], p.E545G, p.E545K, p.Q546E, p.Q546R, p.H1047L, p.H1047R, p.H1047Y), utilizing formalin-fixed paraffin embedded breast tumor tissue, reported as PIK3CA gene mutation status

CMS Annual Lab Meeting June 22, 2020

QIAGEN, LTD.

Presenter: Chaffey, Ben

AGENDA: 2 CDx codes today

- PLA 0155U utilizes tumor tissue (effective January 1, 2020)
- PLA 0177U utilizes plasma (effective April 1, 2020)

- In terms of activities performed in the lab, these two tests differ at the pre-analytical stage.
- However, at the PCR stage, they are essentially identical for the purposes of this discussion.

0155U: Oncology (breast cancer), DNA, PIK3CA gene analysis… utilizing formalin-fixed paraffin embedded breast tumor tissue, reported as PIK3CA gene mutation status
0177U: Oncology (breast cancer), DNA, PIK3CA (phosphatidylinositol-4,5-bisphosphate 3-kinase catalytic subunit alpha) gene analysis of 11 gene variants utilizing plasma, reported as PIK3CA gene mutation status

Public Comment	**Rationale**
81309 X 1.5 ($274.83 X 1.5) <u>81309 description</u> PIK3CA (phosphatidylinositol-4, 5-biphosphate 3-kinase, catalytic subunit alpha) (e.g., colorectal and breast cancer) gene analysis, targeted sequence analysis (e.g., exons 7, 9, and 20)	Similar test methodology performed for both PLA 0155U and PLA 0177U with the same type of results reported

0155U: Oncology (breast cancer), DNA, PIK3CA gene analysis… utilizing formalin-fixed paraffin embedded breast tumor tissue, reported as PIK3CA gene mutation status

- The therascreen PIK3CA RGQ PCR Kit is **a real-time qualitative PCR test for** the detection of 11 mutations in the phosphatidylinositol 3-kinase catalytic subunit alpha (PIK3CA) gene (Exon 7: C420R; Exon 9: E542K, E545A, E545D [1635G>T only], E545G, E545K, Q546E, Q546R; and Exon 20: H1047L, H1047R, H1047Y) using genomic DNA (gDNA) extracted from formalin-fixed, paraffin-embedded (FFPE) **breast tumor tissue** or circulating tumor DNA (ctDNA) from **plasma** derived from K_2EDTA anticoagulated peripheral whole blood taken from patients with breast cancer.
- The test is **intended to aid clinicians in identifying breast cancer patients who may be eligible for treatment with PIQRAY® (alpelisib) based on a PIK3CA Mutation Detected result.** Patients whose FFPE tissue or plasma specimen produces a positive *therascreen* PIK3CA RGQ PCR Kit test result for the presence of one or more PIK3CA mutations are eligible for treatment with PIQRAY (alpelisib).

0155U: Oncology (breast cancer), DNA, PIK3CA gene analysis… utilizing formalin-fixed paraffin embedded breast tumor tissue, reported as PIK3CA gene mutation status

Drug label: PIQRAY® (alpelisib) tablets is indicated in combination with fulvestrant for the treatment of postmenopausal women, and men, with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, PIK3CA-mutated, advanced or metastatic breast cancer as detected by an FDA-approved test following progression on or after an endocrine-based regimen.

0155U: Oncology (breast cancer), DNA, PIK3CA gene analysis… utilizing formalin-fixed paraffin embedded breast tumor tissue, reported as PIK3CA gene mutation status

Public Comment	**Rationale**
81309 X 1.5 ($274.83 X 1.5)	1. The **PIQRAY drug label <u>requires</u> an FDA-approved PIK3CA mutation analysis test be used** to determine treatment eligibility 2. Non-approved tests developed by labs or other manufacturers will report CPT 81309 3. Non-approved tests are not CDx tests: they assess a varying range of mutations, using a range of analytical techniques. They lack clinical validation linking their results to the safe and efficacious use of PIQRAY (alpelisib)

0155U: Oncology (breast cancer), DNA, PIK3CA gene analysis… utilizing formalin-fixed paraffin embedded breast tumor tissue, reported as PIK3CA gene mutation status

Public Comment	**Rationale**
81309 X 1.5 ($274.83 X 1.5)	1. 0155U is proprietary to the QIAGEN *therascreen* PIK3CA RGQ PCR Kit, which was **clinically validated** in the SOLAR-1 trial of alpelisib (André *et al.* N Engl J Med 2019; 380:1929-1940) 2. The test was approved by the FDA by PMA as a companion diagnostic (CDx) for the drug PIQRAY (alpelisib), establishing **clinical utility** 3. It is **the only PCR test approved by the FDA** as a CDx to guide the safe and efficacious use of PIQRAY

0155U: Oncology (breast cancer), DNA, PIK3CA gene analysis… utilizing formalin-fixed paraffin embedded breast tumor tissue, reported as PIK3CA gene mutation status

Public Comment	**Rationale**
81309 X 1.5 ($274.83 X 1.5)	1. Historically, *PIK3CA* testing has been described by 81404, a non-specific code 2. In the 2019 Rate setting meeting, the PIK3CA specific code 81309 was crosswalked directly to 81404 3. Compared to non-CDx tests described by 81309, development of the QIAGEN test required **greater investment**, in order to perform clinical validation and obtain FDA approval as a CDx for PIQRAY by PMA

0155U: Oncology (breast cancer), DNA, PIK3CA gene analysis… utilizing formalin-fixed paraffin embedded breast tumor tissue, reported as PIK3CA gene mutation status

Public Comment	**Rationale**
81309 X 1.5 ($274.83 X 1.5)	1. CDx development, validation and regulatory approval activities required **substantial QIAGEN investment** 2. Maintaining market access to innovative and high-quality CDx tests requires **sustainable reimbursement rates** a) CDx kit cost per test is **$210** (ASP is lower) b) The initial testing lab calculates a **minimum per-test labor and overhead costs of $232**

0155U: Oncology (breast cancer), DNA, PIK3CA gene analysis… utilizing formalin-fixed paraffin embedded breast tumor tissue, reported as PIK3CA gene mutation status

Public Comment	Rationale
81309 X 1.5 ($274.83 X 1.5)	Lab Costs reported to QIAGEN consist of: a) Sample shipping logistics b) Sample receipt and accessioning c) FFPE cutting, staining, and examination d) Sample preparation and testing e) Clinical review and test result analysis f) Pathology sign-out and result reporting g) Tax and freight

0155U: Oncology (breast cancer), DNA, PIK3CA gene analysis… utilizing formalin-fixed paraffin embedded breast tumor tissue, reported as PIK3CA gene mutation status

Lab Managers require sustainable reimbursement*

- "Information on the labor and overhead costs incurred when performing the test was obtained from NeoGenomics Laboratories, a major test provider."
- "…the fee schedule amount for 81404 ($274.83), while apparently adequate to compensate laboratories for older, non-CDx PIK3CA testing, is inadequate to cover the cost of CDx testing of PIK3CA mutations."
- "NeoGenomics has further calculated that the labor and overhead costs of performing the PIK3CA CDx test, above and beyond the cost of the test kit itself, is an additional $232 per single PIK3CA test."

*Letter to CMS July 8, 2019, Re: Crosswalking Proposals for New CPT Code 8XX01: PIK3CA Presented at the June 24, 2019 Clinical Laboratory Fee Schedule Annual Laboratory Meeting

PLA 0177U: Oncology (breast cancer), DNA, PIK3CA (phosphatidylinositol-4,5-bisphosphate 3-kinase catalytic subunit alpha) gene analysis of 11 gene variants utilizing plasma, reported as PIK3CA gene mutation status

CMS Annual Lab Meeting June 22, 2020

QIAGEN, LTD.

Presenter: Chaffey, Ben

Agenda: 2 CDx codes today

- PLA 0177U utilizes plasma
  (effective April 1, 2020)
- PLA 0155U utilizes tumor tissue
  (effective January 1, 2020)

- These two tests differ at the pre-analytical stage, but in the PCR stage at the lab they are essentially identical for the purposes of this discussion.

0155U: Oncology (breast cancer), DNA, PIK3CA gene analysis… utilizing formalin-fixed paraffin embedded breast tumor tissue, reported as PIK3CA gene mutation status
0177U: Oncology (breast cancer), DNA, PIK3CA (phosphatidylinositol-4,5-bisphosphate 3-kinase catalytic subunit alpha) gene analysis of 11 gene variants utilizing plasma, reported as PIK3CA gene mutation status

Public Comment	**Rationale**
81309 X 1.5 ($274.83 X 1.5) <u>81309 description</u> PIK3CA (phosphatidylinositol-4, 5-biphosphate 3-kinase, catalytic subunit alpha) (e.g., colorectal and breast cancer) gene analysis, targeted sequence analysis (e.g., exons 7, 9, and 20)	Similar methodology for both PLA 0155U and PLA 0177U

0177U: Oncology (breast cancer), DNA, PIK3CA (phosphatidylinositol-4,5-bisphosphate 3-kinase catalytic subunit alpha) gene analysis of 11 gene variants utilizing plasma, reported as PIK3CA gene mutation status

- The therascreen PIK3CA RGQ PCR Kit **is a real-time qualitative PCR test for the detection of 11 mutations in the phosphatidylinositol 3-kinase catalytic subunit alpha (PIK3CA) gene** (Exon 7: C420R; Exon 9: E542K, E545A, E545D [1635G>T only], E545G, E545K, Q546E, Q546R; and Exon 20: H1047L, H1047R, H1047Y) using genomic DNA (gDNA) extracted from formalin-fixed, paraffin-embedded (FFPE) **breast tumor tissue** or circulating tumor DNA (ctDNA) from **plasma** derived from K_2EDTA anticoagulated peripheral whole blood taken from patients with breast cancer.
- The test is intended **to aid clinicians in identifying breast cancer patients who may be eligible for treatment with PIQRAY® (alpelisib) based on a PIK3CA Mutation Detected result**. Patients whose FFPE tissue or plasma specimen produces a positive *therascreen* PIK3CA RGQ PCR Kit test result for the presence of one or more PIK3CA mutations are eligible for treatment with PIQRAY (alpelisib).

0177U: Oncology (breast cancer), DNA, PIK3CA (phosphatidylinositol-4,5-bisphosphate 3-kinase catalytic subunit alpha) gene analysis of 11 gene variants utilizing plasma, reported as PIK3CA gene mutation status

Drug label: PIQRAY® (alpelisib) tablets is indicated in combination with fulvestrant for the treatment of postmenopausal women, and men, with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, PIK3CA-mutated, advanced or metastatic breast cancer as detected by an FDA-approved test following progression on or after an endocrine-based regimen.

0177U: Oncology (breast cancer), DNA, PIK3CA (phosphatidylinositol-4,5-bisphosphate 3-kinase catalytic subunit alpha) gene analysis of 11 gene variants utilizing plasma, reported as PIK3CA gene mutation status

Public Comment	**Rationale**
81309 X 1.5 ($274.83 X 1.5)	1. The **PIQRAY drug label <u>requires</u> an FDA-approved PIK3CA mutation analysis test be used** to determine treatment eligibility 2. Non-approved tests developed by labs or other manufacturers will report CPT 81309 3. Non-approved tests are not CDx tests: they assess a varying range of mutations, using a range of analytical techniques. They lack clinical validation linking their results to the safe and efficacious use of PIQRAY (alpelisib)

0177U: Oncology (breast cancer), DNA, PIK3CA (phosphatidylinositol-4,5-bisphosphate 3-kinase catalytic subunit alpha) gene analysis of 11 gene variants utilizing plasma, reported as PIK3CA gene mutation status

Public Comment	**Rationale**
81309 X 1.5 ($274.83 X 1.5)	1. 0177U is proprietary to the QIAGEN *therascreen* PIK3CA RGQ PCR Kit, which was **clinically validated** in the SOLAR-1 trial of alpelisib (André *et al.* N Engl J Med 2019; 380:1929-1940) 2. The test was approved by the FDA by PMA as a companion diagnostic (CDx) for the drug PIQRAY (alpelisib), establishing **clinical utility** 3. It is **the only PCR test approved by the FDA** as a CDx to guide the safe and efficacious use of PIQRAY

0177U: Oncology (breast cancer), DNA, PIK3CA (phosphatidylinositol-4,5-bisphosphate 3-kinase catalytic subunit alpha) gene analysis of 11 gene variants utilizing plasma, reported as PIK3CA gene mutation status

Public Comment	**Rationale**
81309 X 1.5 ($274.83 X 1.5)	1. Historically, *PIK3CA* testing has been described by 81404, a non-specific code 2. In the 2019 Rate setting meeting, the PIK3CA specific code 81309 was crosswalked directly to 81404 3. Compared to non-CDx tests described by 81309, development of the QIAGEN test required **greater investment**, in order to perform clinical validation and obtain FDA approval as a CDx for PIQRAY by PMA

0177U: Oncology (breast cancer), DNA, PIK3CA (phosphatidylinositol-4,5-bisphosphate 3-kinase catalytic subunit alpha) gene analysis of 11 gene variants utilizing plasma, reported as PIK3CA gene mutation status

Public Comment	**Rationale**
81309 X 1.5 ($274.83 X 1.5)	1. CDx development, validation and regulatory approval activities required **substantial QIAGEN investment** 2. Maintaining market access to innovative and high-quality CDx tests requires **sustainable reimbursement rates** a) CDx kit cost per test is **$210** (ASP is lower) b) The initial testing lab calculates a **minimum per-test labor and overhead costs of $232**

0177U: Oncology (breast cancer), DNA, PIK3CA (phosphatidylinositol-4,5-bisphosphate 3-kinase catalytic subunit alpha) gene analysis of 11 gene variants utilizing plasma, reported as PIK3CA gene mutation status

Public Comment	**Rationale**
81309 X 1.5 ($274.83 X 1.5)	Lab Costs reported to QIAGEN consist of: a) Sample shipping logistics b) Sample receipt and accessioning c) Plasma processing d) Sample preparation and testing e) Clinical review and test result analysis f) Pathology sign-out and result reporting g) Tax and freight

0177U: Oncology (breast cancer), DNA, PIK3CA (phosphatidylinositol-4,5-bisphosphate 3-kinase catalytic subunit alpha) gene analysis of 11 gene variants utilizing plasma, reported as PIK3CA gene mutation status

Lab Managers require sustainable reimbursement

- "Information on the labor and overhead costs incurred when performing the test was obtained from NeoGenomics Laboratories, a major test provider."
- "…the fee schedule amount for 81404 ($274.83), while apparently adequate to compensate laboratories for older, non-CDx PIK3CA testing, is inadequate to cover the cost of CDx testing of PIK3CA mutations."
- "NeoGenomics has further calculated that the labor and overhead costs of performing the PIK3CA CDx test, above and beyond the cost of the test kit itself, is an additional $232 per single PIK3CA test."

*Letter to CMS July 8, 2019, Re: Crosswalking Proposals for New CPT Code 8XX01: PIK3CA Presented at the June 24, 2019 Clinical Laboratory Fee Schedule Annual Laboratory Meeting

PLA 0154U: Oncology (urothelial cancer), RNA, analysis by real-time RT-PCR of the FGFR3 (fibroblast growth factor receptor 3) gene analysis (i.e, p.R248C [c.742C>T], p.S249C [c.746C>G], p.G370C [c.1108G>T], p.Y373C [c.1118A>G], FGFR3-TACC3v1, and FGFR3-TACC3v3) utilizing formalin-fixed paraffin-embedded urothelial cancer tumor tissue, reported as FGFR gene alteration status

CMS Annual Lab Meeting June 22, 2020

QIAGEN, LTD.

Presenter: Chaffey, Ben

0154U: Oncology (urothelial cancer), RNA, analysis by real-time RT-PCR of the FGFR3 gene analysis… utilizing formalin-fixed paraffin-embedded urothelial cancer tumor tissue, reported as FGFR gene alteration status

Public Comment	Rationale
<u>81309 description</u> PIK3CA (phosphatidylinositol-4, 5-biphosphate 3-kinase, catalytic subunit alpha) (e.g., colorectal and breast cancer) gene analysis, targeted sequence analysis (e.g., exons 7, 9, and 20) Currently reimbursed at $274.83	A recently-introduced and broadly comparable CPT code, used to describe CDx testing for *PIK3CA* mutations to guide drug use Whilst relevant, it does not completely describe *FGFR* CDx testing

0154U: Oncology (urothelial cancer), RNA, analysis by real-time RT-PCR of the FGFR3 gene analysis… utilizing formalin-fixed paraffin-embedded urothelial cancer tumor tissue, reported as FGFR gene alteration status

The *therascreen* FGFR RGQ RT-PCR Kit is a **real-time, reverse transcription PCR test** for the qualitative detection of two point mutations in exon 7 [p.R248C (c.742C>T), p.S249C (c.746C>G)], two point mutations in exon 10 [p.G370C (c.1108G>T) and p.Y373C (c.1118A>G)] and two fusions (FGFR3-TACC3v1 and FGFR3-TACC3v3) in the fibroblast growth factor receptor 3 (FGFR3) gene in RNA samples derived from formalin fixed paraffin-embedded (FFPE) **urothelial tumor tissue**.

The test is indicated for use as an aid in identifying patients with cases of urothelial cancer (UC) which harbor these alterations and are therefore eligible for treatment with BALVERSA™ (erdafitinib).

0154U: Oncology (urothelial cancer), RNA, analysis by real-time RT-PCR of the FGFR3 gene analysis… utilizing formalin-fixed paraffin-embedded urothelial cancer tumor tissue, reported as FGFR gene alteration status

Drug label: BALVERSA (erdafitinib) is a kinase inhibitor indicated for the treatment of adult patients with locally advanced or metastatic urothelial carcinoma that has

- susceptible FGFR3 or FGFR2 genetic alterations and
- progressed during or following at least one line of prior platinum containing chemotherapy including within 12 months of neoadjuvant or adjuvant platinum-containing chemotherapy.

Select patients for therapy based on an FDA-approved companion diagnostic for BALVERSA.

This indication is approved under accelerated approval based on tumor response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/212018s000lbl.pdf

0154U: Oncology (urothelial cancer), RNA, analysis by real-time RT-PCR of the FGFR3 gene analysis… utilizing formalin-fixed paraffin-embedded urothelial cancer tumor tissue, reported as FGFR gene alteration status

Public Comment	Rationale
81309 X 2 ($274.83 X2)	1. The **BALVERSA drug label <u>requires</u> that an FDA-approved FGFR mutation analysis test be used** to determine treatment eligibility **2. Non-approved tests** developed by labs or other manufacturers **cannot report 0154U** **3. Non-approved tests** are not CDx tests: they assess a varying range of mutations, using a range of analytical techniques. They **lack clinical validation** linking their results to the safe and efficacious use of BALVERSA

0154U: Oncology (urothelial cancer), RNA, analysis by real-time RT-PCR of the FGFR3 gene analysis… utilizing formalin-fixed paraffin-embedded urothelial cancer tumor tissue, reported as FGFR gene alteration status

Public Comment	Rationale
81309 X 2 ($274.83 X2)	1. 0154U is proprietary to QIAGEN FGFR test, which was **clinically validated** in a bridging study to the Clinical Trial Assay used in the BLC2001 Phase II study of erdafitinib (Wang *et al.* J Pathol Clin Res 2020) 2. The test was approved by the FDA by PMA as a companion diagnostic (CDx) to the drug BALVERSA, establishing **clinical utility**

0154U: Oncology (urothelial cancer), RNA, analysis by real-time RT-PCR of the FGFR3 gene analysis… utilizing formalin-fixed paraffin-embedded urothelial cancer tumor tissue, reported as FGFR gene alteration status

Public Comment	Rationale
81309 X 2 ($274.83 X2)	1. *FGFR* alterations are **novel CDx biomarkers**, and historically have not been assessed outside of a research context 2. The QIAGEN *therascreen* FGFR RGQ RT-PCR Kit is **the only IVD PCR test available to detect *FGFR* alterations** 3. It is the **only IVD PCR test approved by the FDA** as a CDx to guide the safe and efficacious use of BALVERSA

0154U: Oncology (urothelial cancer), RNA, analysis by real-time RT-PCR of the FGFR3 gene analysis… utilizing formalin-fixed paraffin-embedded urothelial cancer tumor tissue, reported as FGFR gene alteration status

Public Comment	Rationale
81309 X 2 ($274.83 X2)	The FDA-approved CDx test requires 2 steps: • An **initial step** of Reverse Transcription to create cDNA (complimentary DNA) based upon the tumor-derived RNA sample • A **second step** of multiplex real-time PCR amplification and detection to detect clinically actionable *FGFR3* alterations (both point mutations and gene fusions) in the cDNA

0154U: Oncology (urothelial cancer), RNA, analysis by real-time RT-PCR of the FGFR3 gene analysis… utilizing formalin-fixed paraffin-embedded urothelial cancer tumor tissue, reported as FGFR gene alteration status

Public Comment	Rationale
81309 X 2 ($274.83 X2)	The FDA-approved CDx test analyses a sample of RNA to identify both point mutations and gene fusions. This makes it **more resource intensive** than other PCR tests, which are performed directly on DNA samples: • Additional plastics and reagents for RT (~$80) • Additional 120 minutes for the RT step (60 minutes hands-on time; ~$42) • Utilization of capital equipment (variable)

0154U: Oncology (urothelial cancer), RNA, analysis by real-time RT-PCR of the FGFR3 gene analysis… utilizing formalin-fixed paraffin-embedded urothelial cancer tumor tissue, reported as FGFR gene alteration status

Public Comment	Rationale
81309 X 2 ($274.83 X 2)	CPT 81309 = $274.83 + $274.83 X 0.5 (to recognize status as a CDx test, approved by FDA PMA) = $137.415 + $274.83 X 0.5 (to recognize additional cost of labor, supplies, amortized capital equipment and profit margin) = $137.415 (labor rates vary) **Total = ($274.83 x 2) = $549.66**

0154U: Oncology (urothelial cancer), RNA, analysis by real-time RT-PCR of the FGFR3 gene analysis… utilizing formalin-fixed paraffin-embedded urothelial cancer tumor tissue, reported as FGFR gene alteration status

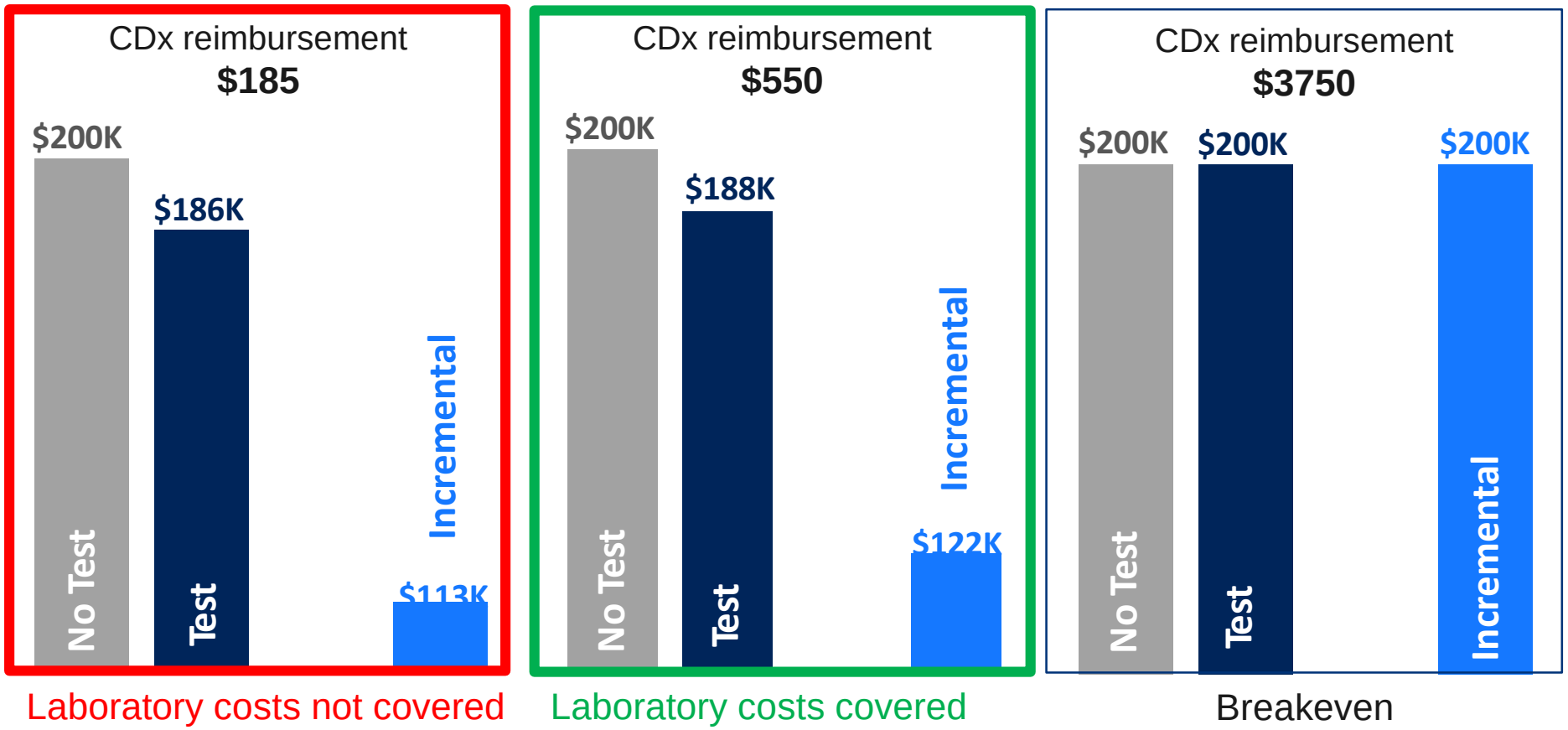
Public Comment	Rationale
81309 X 2 ($274.83 X 2)	1. CDx development, validation and regulatory approval activities required **substantial QIAGEN investment** 2. Maintaining market access to innovative and high-quality CDx tests requires **sustainable reimbursement rates** a) CDx kit list price per test is **$185** (ASP varies) b) An initial testing lab calculates **minimum per-test labor, consumables and overhead costs of $272 (labor rates vary)**

0154U: Oncology (urothelial cancer), RNA, analysis by real-time RT-PCR of the FGFR3 gene analysis… utilizing formalin-fixed paraffin-embedded urothelial cancer tumor tissue, reported as FGFR gene alteration status

Public Comment	Rationale
81309 X 2 ($274.83 X 2)	Lab Costs reported to QIAGEN consist of: a) Sample shipping logistics b) Sample receipt and accessioning c) FFPE cutting, staining, and examination d) Sample preparation and testing e) Clinical review and test result analysis f) Pathology sign-out and result reporting g) Tax and freight

0154U: Oncology (urothelial cancer), RNA, analysis by real-time RT-PCR of the FGFR3 gene analysis… utilizing formalin-fixed paraffin-embedded urothelial cancer tumor tissue, reported as FGFR gene alteration status

Modeled Average Cost per Responder for 100 patients



Laboratory costs not covered | Laboratory costs covered | Breakeven

Cost is per 100 patients treated for mUC over a 12 week* period and started with approved therapies at US list prices. *NCCN (2019) NCCN clinical practice guidelines in Oncology Bladder cancer. Version 5.2020

0154U: Oncology (urothelial cancer), RNA, analysis by real-time RT-PCR of the FGFR3 gene analysis… utilizing formalin-fixed paraffin-embedded urothelial cancer tumor tissue, reported as FGFR gene alteration status

Public Comment	**Rationale**
81309 X 2 ($274.83 X 2)	1. **Correctly identify the clinically actionable *FGFR3* mutations** 2. **Enable selection of patients** who will likely respond to Rx treatment 3. **Eliminate the costs** associated with inappropriate use of BALVERSA (erdafitinib) 4. Help **avoid the costs associated with the use of other less effective treatments** for a subset of patients (data pending)

Questions