

0211U

Oncology (pan-tumor), DNA and RNA by next generation sequencing, utilizing formalin-fixed paraffin-embedded tissue, interpretative report for single nucleotide variants, copy number alterations, tumor mutational burden, and microsatellite instability, with therapy association

0211U: MI Cancer Seek™ - NGS analysis C.

Public Comment

- Recommendation to crosswalk 0211U to 0019U (NLA=\$3675.00) + 0036U (NLA=\$4780.00)
- 1x multiplier for each
- Recommendation of an NLA equal to \$8455 for 0211U

Rationale

MI Cancer Seek is a combined whole transcriptome AND whole exome sequencing test that is equivalent to performing both:

- 0019U: Oncology, RNA, gene expression by whole transcriptome sequencing, formalin-fixed paraffin-embedded tissue or fresh frozen tissue, predictive algorithm reported as potential targets for therapeutic agents
- 0036U: Exome (ie, somatic mutations), paired formalin-fixed paraffin-embedded tumor tissue and normal specimen, sequence analyses

0211U: MI Cancer Seek™ - NGS analysis C.

	0019U*	0211U	0036U**
Assay type	Whole Transcriptome Sequencing	Whole Transcriptome Sequencing Whole Exome Sequencing	Whole Exome Sequencing
Platform	NGS RNASeq	NGS (Illumina) RNASeq & DNASEq	NGS (Illumina) DNASEq
Samples tested	FFPE & frozen tumor tissue	FFPE tumor tissue	FFPE tumor tissue & paired normal tissue
Sequencing coverage	Interrogation of whole transcriptome	Unbiased interrogation of >20,000 genes and interrogation of the whole transcriptome	Unbiased interrogation of >20,000 genes
Analysis and reporting	<ul style="list-style-type: none"> • Uses RNA transcript data to identify aberrantly activated proteins • Algorithm-based reporting • Tumor-specific results support optimal treatment decisions 	<ul style="list-style-type: none"> • Uses RNA transcript data to identify aberrantly activated proteins • Identifies DNA-based driver mutations • Mutation classification based on clinical relevance in accordance with public data and internally-developed knowledge • Algorithm-based reporting • Tumor-specific results support optimal treatment decisions 	<ul style="list-style-type: none"> • Identifies DNA-based driver mutations • Mutation classification based on clinical relevance in accordance with public data and internally-developed knowledge • Tumor-specific results support optimal treatment decisions

*[Website](#) information for Darwin OncoTarget™/OncoTreat™

**[Website](#) information for EXaCT-1 test

Table of Recommendations: Various Red Cell Antigen Tests
 0180U – 0201U via Sanger Sequencing (revised post-presentation)
 0221U and 0222U via Next Generation Sequencing (no revisions)

Summary of revisions: Our recommended approach to crosswalk 0180U through 0201U to the most appropriate molecular pathology (MoPath) code remains unchanged. However, revisions to the specific MoPath code have been made to better match the code descriptors. Below is a summary of revisions. The slides that follow contain the final recommendations for codes 0180U – 0201U

PLA Code and Short Descriptor	Original Recommendation	Revised	PLA Code and Short Descriptor	Original Recommendation	Revised
0180U ABO GNOTYP ABO 7 EXONS	crosswalk to CPT 81405	(no revision)	0192U JK GNOTYP SLC14A1 EXON 9	crosswalk to CPT 81405	To CPT 81404
0181U CO GNOTYP AQP1 EXON 1	crosswalk to CPT 81404	To CPT 81403	0193U JR GNOTYP ABCG2 EXONS 2-26	crosswalk to CPT 81405	To CPT 81406
0182U CROM GNOTYP CD55 EXONS 1-10	crosswalk to CPT 81405	(no revision)	0194U KEL GNOTYP KEL EXON 8	crosswalk to CPT 81405	To CPT 81403
0183U DI GNOTYP SLC4A1 EXON 19	crosswalk to CPT 81405	To CPT 81403	0195U KLF1 TARGETED SEQUENCING	crosswalk to CPT 81404	To CPT 81403
0184U DO GNOTYP ART4 EXON 2	crosswalk to CPT 81404	To CPT 81403	0196U LU GNOTYP BCAM EXON 3	crosswalk to CPT 81405	To CPT 81403
0185U FUT1 GNOTYP FUT1 EXON 4	crosswalk to CPT 81403	(no revision)	0197U LW GNOTYP ICAM4 EXON 1	crosswalk to CPT 81404	To CPT 81403
0186U FUT2 GNOTYP FUT2 EXON 2	crosswalk to CPT 81403	(no revision)	0198U RHD&RHCE GNTYP RHD1-10&RHCE5	crosswalk to CPT 81405	To CPT 81406
0187U FY GNOTYP ACKR1 EXONS 1-2	crosswalk to CPT 81403	To CPT 81404	0199U SC GNOTYP ERMAP EXONS 4 12	crosswalk to CPT 81405	To CPT 81404
0188U GE GNOTYP GYPC EXONS 1-4	crosswalk to CPT 81404	(no revision)	0200U XK GNOTYP XK EXONS 1-3	crosswalk to CPT 81404	(no revision)
0189U GYPA GNOTYP NTRNS 1 5 EXON 2	crosswalk to CPT 81405	To CPT 81404	0201U YT GNOTYP ACHE EXON 2	crosswalk to CPT 81404	To CPT 81403
0190U GYPB GNOTYP NTRNS 1 5 SEUX 3	crosswalk to CPT 81405	To CPT 81404	0221U (ABO, NGS)*	gapfill	(no revision)
0191U IN GNOTYP CD44 EXONS 2 3 6	crosswalk to CPT 81405	To CPT 81404	0222U (RH, NGS)*	gapfill	(no revision)

*Not an official AMA short descriptor

0180U

Red cell antigen (ABO blood group) genotyping (ABO), gene analysis Sanger/chain termination/conventional sequencing, *ABO (ABO, alpha 1-3-N-acetylgalactosaminyltransferase and alpha 1-3-galactosyltransferase)* gene, including subtyping, 7 exons

0180U: Navigator ABO Sequencing, Grifols Immunohematology Center

Public Comment

- Final recommendation: crosswalk to CPT 81405
- 1x multiplier for each
- Recommend NLA for 0180U: \$301.35

Rationale

0180U reports the analysis of 7 exons of *ABO* using Sanger sequencing. This procedure fits the descriptor and an example for CPT 81405

“Molecular pathology procedure, Level 6 (e.g., analysis of 6-10 exons by DNA sequence analysis, mutation scanning or duplication/deletion variants of 11-25 exons, regionally targeted cytogenomic array analysis)” ~AMA

0181U

Red cell antigen (Colton blood group) genotyping (CO), gene analysis, *AQP1* (*aquaporin 1 [Colton blood group]*) exon 1

0181U: Navigator CO Sequencing, Grifols Immunohematology Center

Public Comment

- Final recommendation: crosswalk to CPT 81403
- 1x multiplier for each
- Recommend NLA for 0181U: \$185.20

Rationale

0181U reports the analysis of *CO* exon 1 using Sanger sequencing. This procedure fits the descriptor and an example for CPT 81403

“Molecular pathology procedure, Level 4 (eg, analysis of single exon by DNA sequence analysis, analysis of >10 amplicons using multiplex PCR in 2 or more independent reactions, mutation scanning or duplication/deletion variants of 2-5 exons)” ~ AMA

0182U

Red cell antigen (Cromer blood group) genotyping (CROM),
gene analysis, *CD55* (*CD55 molecule [Cromer blood group]*)
exons 1-10

0182U: Navigator CROM Sequencing, Grifols Immunohematology Center

Public Comment

- Final recommendation: crosswalk to CPT 81405
- 1x multiplier for each
- Recommend NLA for 0182U: \$301.35

Rationale

0182U reports the analysis of *CROM* exons 1 to 10 using Sanger sequencing. This procedure fits the descriptor and an example for CPT 81405

“Molecular pathology procedure, Level 6 (e.g., analysis of 6-10 exons by DNA sequence analysis, mutation scanning or duplication/deletion variants of 11-25 exons, regionally targeted cytogenomic array analysis)” ~AMA

0183U

Red cell antigen (Diego blood group) genotyping (DI), gene analysis, *SLC4A1* (*solute carrier family 4 member 1 [Diego blood group]*) exon 19

0183U: Navigator DI Sequencing, Grifols Immunohematology Center

Public Comment

- Final recommendation: crosswalk to CPT 81403
- 1x multiplier for each
- Recommend NLA for 0183U: \$185.20

Rationale

0183U reports the analysis of *DI* exon 19 using Sanger sequencing. This procedure fits the descriptor and an example for CPT 81403

“Molecular pathology procedure, Level 4 (eg, analysis of single exon by DNA sequence analysis, analysis of >10 amplicons using multiplex PCR in 2 or more independent reactions, mutation scanning or duplication/deletion variants of 2-5 exons)” ~ AMA

0184U

Red cell antigen (Dombrock blood group) genotyping (DO),
gene analysis, *ART4* (*ADP-ribosyltransferase 4 [Dombrock
blood group]*) exon 2

0184U: Navigator DO Sequencing, Grifols Immunohematology Center

Public Comment

- Final recommendation: crosswalk to CPT 81403
- 1x multiplier for each
- Recommend NLA for 0184U: \$185.20

Rationale

0184U reports the analysis of *DO* exon 2 using Sanger sequencing. This procedure fits the descriptor and an example for CPT 81403

“Molecular pathology procedure, Level 4 (eg, analysis of single exon by DNA sequence analysis, analysis of >10 amplicons using multiplex PCR in 2 or more independent reactions, mutation scanning or duplication/deletion variants of 2-5 exons)” ~ AMA

0185U

Red cell antigen (H blood group) genotyping (FUT1), gene analysis, *FUT1 (fucosyltransferase 1 [H blood group])* exon 4

0185U: Navigator FUT1 Sequencing, Grifols Immunohematology Center

Public Comment

- Final recommendation: crosswalk to CPT 81403
- 1x multiplier for each
- Recommend NLA for 0185U: \$185.20

Rationale

0185U reports the analysis of *FUT1* exon 4 using Sanger sequencing. This procedure fits the descriptor and an example for CPT 81403

“Molecular pathology procedure, Level 4 (eg, analysis of single exon by DNA sequence analysis, analysis of >10 amplicons using multiplex PCR in 2 or more independent reactions, mutation scanning or duplication/deletion variants of 2-5 exons)” ~ AMA

0186U

Red cell antigen (H blood group) genotyping (FUT2), gene analysis, *FUT2 (fucosyltransferase 2)* exon 2

0186U: Navigator FUT2 Sequencing, Grifols Immunohematology Center

Public Comment

- Final recommendation: crosswalk to CPT 81403
- 1x multiplier for each
- Recommend NLA for 0186U: \$185.20

Rationale

0186U reports the analysis of *FUT2* exon 2 using Sanger sequencing. This procedure fits the descriptor and an example for CPT 81403

“Molecular pathology procedure, Level 4 (eg, analysis of single exon by DNA sequence analysis, analysis of >10 amplicons using multiplex PCR in 2 or more independent reactions, mutation scanning or duplication/deletion variants of 2-5 exons)” ~ AMA

0187U

Red cell antigen (Duffy blood group) genotyping (FY), gene analysis, *ACKR1* (*atypical chemokine receptor 1 [Duffy blood group]*) exons 1-2

0187U: Navigator FY Sequencing, Grifols Immunohematology Center

Public Comment

- Final recommendation: crosswalk to CPT 81404
- 1x multiplier for each
- Recommend NLA for 0187U \$274.83

Rationale

0187U reports the analysis of *FY* exons 1 and 2 using Sanger sequencing. This procedure fits the descriptor and an example for CPT 81404

“Molecular pathology procedure, Level 5 (eg, analysis of 2-5 exons by DNA sequence analysis, mutation scanning or duplication/deletion variants of 6-10 exons, or characterization of a dynamic mutation disorder/triplet repeat by Southern blot analysis) ” ~AMA

0188U

Red cell antigen (Gerbich blood group) genotyping (GE), gene analysis, *GYPC* (*glycophorin C [Gerbich blood group]*) exons 1-4

0188U: Navigator GE Sequencing, Grifols Immunohematology Center

Public Comment

- Final recommendation: crosswalk to CPT 81404
- 1x multiplier for each
- Recommend NLA for 0188U: \$274.83

Rationale

0188U reports the analysis of *GE* exons 1 to 4 using Sanger sequencing. This procedure fits the descriptor and an example for CPT 81404

“Molecular pathology procedure, Level 5 (eg, analysis of 2-5 exons by DNA sequence analysis, mutation scanning or duplication/deletion variants of 6-10 exons, or characterization of a dynamic mutation disorder/triplet repeat by Southern blot analysis) ” ~ AMA

0189U

Red cell antigen (MNS blood group) genotyping (GYPA), gene analysis, *GYPA (glycophorin A [MNS blood group])* introns 1, 5, exon 2

0189U: Navigator GYPA Sequencing, Grifols Immunohematology Center

Public Comment

- Final recommendation: crosswalk to CPT 81404
- 1x multiplier for each
- Recommend NLA for 0189U: \$ 274.83

Rationale

0189U reports the analysis of *GYPA* introns 1, 5 and exon 2 using Sanger sequencing. This procedure fits the descriptor and an example for CPT 81404

“Molecular pathology procedure, Level 5 (eg, analysis of 2-5 exons by DNA sequence analysis, mutation scanning or duplication/deletion variants of 6-10 exons, or characterization of a dynamic mutation disorder/triplet repeat by Southern blot analysis) ” ~ AMA

0190U

Red cell antigen (MNS blood group) genotyping (GYPB), gene analysis, *GYPB (glycophorin B [MNS blood group])* introns 1, 5, pseudoexon 3

0190U: Navigator GYPB Sequencing, Grifols Immunohematology Center

Public Comment

- Final recommendation: crosswalk to CPT 81404
- 1x multiplier for each
- Recommend NLA for 0190U: \$ 274.83

Rationale

0190U reports the analysis of *GYPB* introns 1, 5, and pseudoexon 3 using Sanger sequencing. This procedure fits the descriptor and an example for CPT 81404

“Molecular pathology procedure, Level 5 (eg, analysis of 2-5 exons by DNA sequence analysis, mutation scanning or duplication/deletion variants of 6-10 exons, or characterization of a dynamic mutation disorder/triplet repeat by Southern blot analysis) ” ~ AMA

0191U

Red cell antigen (Indian blood group) genotyping (IN), gene analysis, *CD44* (*CD44 molecule [Indian blood group]*) exons 2, 3, 6

0191U: Navigator IN Sequencing, Grifols Immunohematology Center

Public Comment

- Final recommendation: crosswalk to CPT 81404
- 1x multiplier for each
- Recommend NLA for 0191U: \$274.83

Rationale

0191U reports the analysis of *IN* exons 2, 3, 6 using Sanger sequencing. This procedure fits the descriptor and an example for CPT 81404

“Molecular pathology procedure, Level 5 (eg, analysis of 2-5 exons by DNA sequence analysis, mutation scanning or duplication/deletion variants of 6-10 exons, or characterization of a dynamic mutation disorder/triplet repeat by Southern blot analysis) ” ~ AMA

0192U

Red cell antigen (Kidd blood group) genotyping (JK), gene analysis, *SLC14A1* (*solute carrier family 14 member 1 [Kidd blood group]*) gene promoter, exon 9

0192U: Navigator JK Sequencing, Grifols Immunohematology Center

Public Comment

- Final recommendation: crosswalk to CPT 81404
- 1x multiplier for each
- Recommend NLA for 0192U: \$ 274.83

Rationale

0192U reports the analysis of *JK* exon 9 and promoter region using Sanger sequencing. This procedure fits the descriptor and an example for CPT 81404

“Molecular pathology procedure, Level 5 (eg, analysis of 2-5 exons by DNA sequence analysis, mutation scanning or duplication/deletion variants of 6-10 exons, or characterization of a dynamic mutation disorder/triplet repeat by Southern blot analysis) ” ~ AMA

0193U

Red cell antigen (JR blood group) genotyping (JR), gene analysis, ABCG2 (ATP binding cassette subfamily G member 2 [Junior blood group]) exons 2-26

0193U: Navigator JR Sequencing, Grifols Immunohematology Center

Public Comment

- Final recommendation: crosswalk to CPT 81406
- 1x multiplier for each
- Recommend NLA for 0193U: \$282.88

Rationale

0193U reports the analysis of *JR* exons 2 to 26 using Sanger sequencing. This procedure fits the descriptor and an example for CPT 81406

“Molecular pathology procedure, Level 7, (e.g., analysis of 11-25 exons by DNA sequence analysis, mutation scanning or duplication/deletion variants of 26-50 exons, cytogenomic array analysis for neoplasia)” ~AMA

0194U

Red cell antigen (Kell blood group) genotyping (KEL), gene analysis, *KEL (Kell metallo-endopeptidase [Kell blood group])*
exon 8

0194U: Navigator KEL Sequencing, Grifols Immunohematology Center

Public Comment

- Final recommendation: crosswalk to CPT 81403
- 1x multiplier for each
- Recommend NLA for 0194U: \$185.20

Rationale

0194U reports the analysis of *KEL* exon 8 using Sanger sequencing. This procedure fits the descriptor and an example for CPT 81403

“Molecular pathology procedure, Level 4 (eg, analysis of single exon by DNA sequence analysis, analysis of >10 amplicons using multiplex PCR in 2 or more independent reactions, mutation scanning or duplication/deletion variants of 2-5 exons)” ~ AMA

0195U

KLF1 (*Kruppel-like factor 1*), targeted sequencing (ie, exon 13)

0195U: Navigator KLF1 Sequencing, Grifols Immunohematology Center

Public Comment

- Final recommendation: crosswalk to CPT 81403
- 1x multiplier for each
- Recommend NLA for 0195U: \$185.20

Rationale

0195U reports the analysis of *KLF1* exons 13 using Sanger sequencing. This procedure fits the descriptor and an example for CPT 81403

“Molecular pathology procedure, Level 4 (eg, analysis of single exon by DNA sequence analysis, analysis of >10 amplicons using multiplex PCR in 2 or more independent reactions, mutation scanning or duplication/deletion variants of 2-5 exons)” ~ AMA

0196U

Red cell antigen (Lutheran blood group) genotyping (LU), gene analysis, *BCAM* (*basal cell adhesion molecule [Lutheran blood group]*) exon 3

0196U: Navigator LU Sequencing, Grifols Immunohematology Center

Public Comment

- Final recommendation: crosswalk to CPT 81403
- 1x multiplier for each
- Recommend NLA for 0196U: \$185.20

Rationale

0196U reports the analysis of *LU* exons 3 using Sanger sequencing. This procedure fits the descriptor and an example for CPT 81403

“Molecular pathology procedure, Level 4 (eg, analysis of single exon by DNA sequence analysis, analysis of >10 amplicons using multiplex PCR in 2 or more independent reactions, mutation scanning or duplication/deletion variants of 2-5 exons)” ~ AMA

0197U

Red cell antigen (Landsteiner-Wiener blood group)
genotyping (LW), gene analysis, *ICAM4* (*intercellular adhesion
molecule 4 [Landsteiner-Wiener blood group]*) exon 1

0197U: Navigator LW Sequencing, Grifols Immunohematology Center

Public Comment

- Final recommendation: crosswalk to CPT 81403
- 1x multiplier for each
- Recommend NLA for 0197U: \$185.20

Rationale

0197U reports the analysis of *LW* exon 1 using Sanger sequencing. This procedure fits the descriptor and an example for CPT 81403

“Molecular pathology procedure, Level 4 (eg, analysis of single exon by DNA sequence analysis, analysis of >10 amplicons using multiplex PCR in 2 or more independent reactions, mutation scanning or duplication/deletion variants of 2-5 exons)” ~ AMA

0198U

Red cell antigen (RH blood group) genotyping (RHD and RHCE), gene analysis Sanger/chain termination/conventional sequencing, *RHD* (*Rh blood group D antigen*) exons 1-10 and RHCE (*Rh blood group CcEe antigens*) exon 5

0198U: Navigator RHD/CE Sequencing, Grifols Immunohematology Center

Public Comment

- Final recommendation: crosswalk to CPT 81406
- 1x multiplier for each
- Recommend NLA for 0198U: \$282.88

Rationale

0198U reports the analysis of *RHD* exons 1 to 10 and *RHCE* exon 5 using Sanger sequencing. This procedure fits the descriptor and an example for CPT 81406

““Molecular pathology procedure, Level 7, (e.g., analysis of 11-25 exons by DNA sequence analysis, mutation scanning or duplication/deletion variants of 26-50 exons, cytogenomic array analysis for neoplasia)” ~AMA

0199U

Red cell antigen (Scianna blood group) genotyping (SC), gene analysis, *ERMAP* (*erythroblast membrane associated protein* [*Scianna blood group*]) exons 4, 12

0199U: Navigator SC Sequencing, Grifols Immunohematology Center

Public Comment

- Final recommendation: crosswalk to CPT 81404
- 1x multiplier for each
- Recommend NLA for 0199U: \$ 274.83

Rationale

0199U reports the analysis of SC exons 4, 12 using Sanger sequencing. This procedure fits the descriptor and an example for CPT 81404

“Molecular pathology procedure, Level 5 (eg, analysis of 2-5 exons by DNA sequence analysis, mutation scanning or duplication/deletion variants of 6-10 exons, or characterization of a dynamic mutation disorder/triplet repeat by Southern blot analysis) ” ~ AMA

0200U

Red cell antigen (Kx blood group) genotyping (XK), gene analysis, *XK (X-linked Kx blood group)* exons 1-3

0200U: Navigator XK Sequencing, Grifols Immunohematology Center

Public Comment

- Final recommendation: crosswalk to CPT 81404
- 1x multiplier for each
- Recommend NLA for 0200U: \$274.83

Rationale

0200U reports the analysis of *XK* exons 1 to 3 using Sanger sequencing. This procedure fits the descriptor and an example for CPT 81404

“Molecular pathology procedure, Level 5 (eg, analysis of 2-5 exons by DNA sequence analysis, mutation scanning or duplication/deletion variants of 6-10 exons, or characterization of a dynamic mutation disorder/triplet repeat by Southern blot analysis) ” ~ AMA

0201U

Red cell antigen (Yt blood group) genotyping (YT), gene analysis, *ACHE* (*acetylcholinesterase [Cartwright blood group]*)
exon 2

0201U: Navigator YT Sequencing, Grifols Immunohematology Center

Public Comment

- Final recommendation: crosswalk to CPT 81403
- 1x multiplier for each
- Recommend NLA for 0201U: \$185.20

Rationale

0201U reports the analysis of *YT* exon 2 using Sanger sequencing. This procedure fits the descriptor and an example for CPT 81403

“Molecular pathology procedure, Level 4 (eg, analysis of single exon by DNA sequence analysis, analysis of >10 amplicons using multiplex PCR in 2 or more independent reactions, mutation scanning or duplication/deletion variants of 2-5 exons)” ~ AMA

0221U

Red cell antigen (ABO blood group) genotyping (ABO), gene analysis, next-generation sequencing, ABO (ABO, alpha 1-3-N-acetylgalactosaminyltransferase and alpha 1-3-galactosyltransferase) gene

0221U: Navigator ABO Blood Group NGS, Grifols Immunoematology Center

Public Comment

- Final recommendation to gapfill
- Test resource calculation based on average of 4 samples per run

Rationale

There is not a comparable, coded CLDT to NGS test for ABO typing and subtyping

Resources required to run the test:

Logistics		\$16.50
Reagents – Extraction	\$5.50	
Reagents – Amplification	\$163.01	
Next-Gen sequencing reagents:	\$447.90	
Labor – Technician & Director		\$334.40
Dedicated instrument depreciation	\$70.86	
Overhead		\$184.92
Total resources		\$1223.09

0222U

Red cell antigen (RH blood group) genotyping (RHD and RHCE), gene analysis, next-generation sequencing, RH proximal promoter, exons 1-10, portions of introns 2-3

0222U: Navigator Rh Blood Group NGS, Grifols Immunoematology Center

Public Comment

- Final recommendation to gapfill
- Test resource calculation based on average of 5.25 samples per run

Rationale

There is not a comparable, coded CLDT to NGS test for RHD + RHCE analysis

Resources required to run the test:

Logistics		\$16.50
Reagents – Extraction	\$5.50	
Reagents – Amplification	\$217.07	
Next-Gen sequencing reagents:	\$336.36	
Labor – Technician & Director		\$388.80
Dedicated instrument depreciation	\$70.86	
Overhead		\$167.68
Total resources		\$1202.77