February 1, 2018

RE: Nebraska Methodist Hospital Pathology Center Special Bulletin
ANNUAL NOTICE TO PHYSICIANS 2018

Dear Partner,

We are enclosing for your review the Annual Notice to Physicians for medical necessity, reflex testing, and 2018 CPT code changes. The Office of Inspector General (OIG) requires that laboratories send this information annually to ordering physicians. Please forward copies to your billing office and other pertinent personnel as well as retaining for your records.

If you require additional copies of the bulletin or require clarification of the information presented, please contact a pathologist at 402-354-4541. A copy of these documents will be posted on the Pathology Center Website as well as the Methodist Hospital Intranet.

Thank you.

ANNUAL NOTICE TO PHYSICIANS
2018

Nebraska Methodist Hospital Pathology Center is providing physician clients with an annual notice of our commitment to adhere to all federal and state laws and program requirements for federal, state, and private health plans. This annual notice is in compliance with the regulations and requirements of the Office of Inspector General (OIG) of the Department of Health and Human Services, and the Center for Medicare and Medicaid Services (CMS).

The information below is provided to promote awareness of federal regulations and explain your need to provide documentation when ordering testing services for federally insured patients.

MEDICAL NECESSITY

Medicare will pay only for tests that meet the Medicare coverage criteria and are "reasonable and necessary to treat or diagnose an individual patient". *Section 1862 (a) (1) (A) of the Social Security Act.*

When instructing us to seek Medicare reimbursement, you must order only those tests that you believe to be medically necessary for patient diagnosis and treatment. This includes any and all tests that are components of ordered panels.

As a provider, you are responsible to:

- document medical necessity for each test in the permanent patient medical record
- **provide appropriate diagnostic information in the form of ICD-10 code**(s) (beginning October 1, 2015) with any test(s) for which you instruct us to seek Medicare reimbursements.
- provide complete information for billing including copies of the patient's primary and secondary insurance, policy holder and date of birth of policy holder, guarantor, diagnosis codes, and prior authorization, when it is required. If prior authorization is required, the authorization number received from the insurance provider **must** also be provided to the laboratory at the time of service.

Failure to provide the required demographic information will result in follow up inquiries and denied laboratory charges will be billed to the client and ordering provider account.

As a provider, you are responsible for assuring the completion of an Advance Beneficiary Notice (ABN) in the circumstances outlined below.

ADVANCE BENEFICIARY NOTICES (ABN)

Medicare can deny reimbursement for tests based upon absence of medical necessity, routine health screening, investigational use only tests and frequency limitations. An ABN signed by the patient prior to service is necessary to document that the patient is aware that Medicare may not pay for a test and that the patient has agreed to pay for the testing in the event that Medicare payment is denied.

The following reasons are commonly provided by Medicare when claims are denied:

- Medicare does not usually pay for this service for the diagnosis provided.
- Medicare will not pay for research or investigational use tests.
- Medicare does not pay for this service based on frequency limitations.
- Medicare does not pay for most routine screening tests.
- Medicare does not pay for annual physical exams.

If you order a test that Medicare is likely to deny payment on, the laboratory requisition must be accompanied by an appropriately completed ABN. ABN's must be obtained prior to specimen collection and/or the service being performed. Patients presenting directly to a Methodist Pathology Center associated facility or draw center to have blood drawn will be screened for the necessity of an ABN prior to the specimen collection. Patient specimens collected at Methodist Pathology Center client sites must be screened by the client. If an ABN is necessary, a copy of the completed ABN must be sent to the laboratory with the test requisition and the specimen.

Each ABN must be specific to each laboratory test ordered. Each test must be accompanied by the specific reason that Medicare might not pay for the test. Blanket waivers for all tests ordered on a Medicare patient are not allowed by Medicare and will not be accepted by Methodist Pathology Center.

Without a signed ABN, the patient has no obligation to pay for the service. When payment for services are denied due to lack of medical necessity, inappropriate medical necessity, or lack of ABN documentation, Methodist Pathology Center will notify the physician, client and/or clinic of the issue. Methodist Pathology Center will document these occurrence issues and if not remedied, your client account may be billed directly. If you have questions concerning documentation, please contact Client Services at (402) 354-4541.

PREAUTHORIZATION

Preauthorization from the patient's healthcare plan carrier is required for many esoteric and molecular or genetic tests. Once you have confirmed preauthorization, please attach this documentation to the requisition accompanying the specimen to assure appropriate billing. **If preauthorization for Molecular/Genetic testing is not confirmed prior to collection and testing, your practice and/or your patient may be responsible for the expense**. Contact Client Services at (402)354-4541 to address any questions you may have.

CUSTOM PROFILES

Use of custom profiles is strongly discouraged. If a physician requests a customized test order profile, a signed physician acknowledgement is required from each physician who will be ordering the custom profile. Federal regulations require that acknowledgment forms be signed annually and returned to the laboratory. Physician acknowledgements will affirm:

- The custom test order profile was created at the request of the physician(s).
- The physician is informed of the amount Medicare will reimburse for each test included in the custom profile.
- The physician(s) will order individual tests or a less inclusive profile when one or more of the tests in the customized profile is not medically necessary for the patient.

2018 CPT CHANGES

The American Medical Association (AMA) has made many additions, deletions and description changes to the CPT 2018 coding manual that apply to Pathology services and additional modification of Molecular testing codes remains under review. These changes occurred on January 1, 2018. If you have questions concerning CPT code changes, please contact a Client Services Representative at (402) 354-4541.

REFLEX TESTING

When defined criteria are met for some laboratory tests, additional testing will be automatically be performed to provide more conclusive laboratory information for diagnosis and treatment. The CPT coding will accurately reflect the testing that is performed. If you determine that reflex testing is not medically necessary for your patient, you may opt out by indicating on the requisition only the specific test or component necessary and writing “no reflex” on the requisition.

Please refer to the list attached for the current reflex testing cascades used at Methodist Pathology Center. Esoteric testing not performed at Methodist Pathology Center is sent to outside referral laboratories. These referral laboratories also utilize reflex testing cascades. Some of the more common referral laboratory reflex tests are also listed. If you have any questions regarding reflex testing, please contact Client Services to reach a Pathologist at (402) 354-4541.

PATIENT SPECIMEN IDENTIFICATION

All re-collectable specimens (Blood, Urine, Stool, Culture Swabs) must be clearly labeled with two unique patient identifiers.
The 2nd Identifier/Correction Verification form will no longer be used**. Any specimens submitted to the Pathology Center without two identifiers will be rejected and will need to be recollected.**

Acceptable non-patient specimens (Outreach Clients)

- Specimens are labeled with the patient’s first and last name and one unique identifying number. This number may be a unique identifier such as:
    - The patient’s date of birth, Social Security Number, Unique identifying number (e.g., medical record number), A LIS bar code

Optimal labeling of specimens would include Full Patient Name, Date of Birth, Date and Time of collection and initials of person who obtained the specimen.

METHODIST The Pathology Center

January 30, 2018

TO: All Methodist Pathology Center Clients
FROM: Lynette Jelden, Business Operations Manager, Laboratory Client Services
RE: Genetic Testing Prior Authorization

Molecular/genetic testing can play an important role in making a definitive diagnosis to treat the patient appropriately. However, because of the high costs associated with this testing, most insurance plans now require prior authorization. Below is a summary of common CPT that will be reviewed by most insurance providers for Prior Authorization.

- Tier 1 Molecular Pathology Procedures
- Tier 2 Molecular Pathology Procedures
- Genomic Sequencing Procedures
- Multianalyte Assays with Algorithmic Analyses that include Molecular Pathology Testing
- These CPT® codes:
  - 0001U
  - 0004M - 0008M
  - 81161 - 81421
  - 81423 - 81479
  - 81507
  - 81519
  - 81545 – 81599

Pre-authorization must be obtained by the ordering provider before the tests are collected. This process can take several days and testing can not be held in the Pathology Center while waiting for pre-authorization. The Pathology Center will not delay testing of specimens received in the laboratory. Without pre-authorization, some molecular/genetic testing will not be covered by the patient's insurance provider. **If the insurance provider does not pay for the cost of testing due to lack of prior-authorization, the client account could be billed for the cost of the test.**

We ask that before the specimen is scheduled to be drawn or slides be pulled for additional testing, that the patient's insurance is verified for eligibility and it has been confirmed and documented whether prior authorization is required and it has been initiated.

Attached is a list of genetic tests that are orderable through Methodist Pathology. This list is not all inclusive and could change without notice. Please call Methodist Pathology at 402.354.4540 with any questions.

GENETIC & MOLECULAR PRIOR AUTHORIZATION REQUIRED 2018	
Tier 1 Molecular Pathology Procedures	
Tier 2 Molecular Pathology Procedures	
Genomic Sequencing Procedures	
Multianalyte Assays with Algorithmic Analyses that include Molecular Pathology Testing	
CPT Codes Include:	**All Patients covered by United Healthcare are required to obtain prior authorization using the Beach LBS tool**
0001U	
0004M - 0008M	
81161 – 81421	
81423 – 81479	
81507	
81519	
81545 – 81599	
0009M (Starting Jan 1, 2018)	
S3870 (Starting Jan 1, 2018)	
APC Resistance reflex to Factor V Leiden	See Leiden factor V by PCR 85307 /81241
BCR/ABL by PCR, Qualitative	81206 / 81207
BCR/ABL by PCR, Quantitiative	81206
BRAF	81210
CGH Microarray	Varies (includes 81406 or 81229, 88239 or 88237 or 88233 or 88235 dependent upon Specimen type)
Chromosome, Amniotic	Varies (includes 88285/88280/88261/82106, 88235 x2 88269)
Chromosome, Blood	Varies (includes 88285 x3 /88280 x2 /88261 / 88230 x2 /88289)
Chromosome, Bone Marrow	Varies (includes 88285/88280/88261/88237)
Chromosome FISH	Varies (includes 88271 x varies, 88275 x varies)
Chromosome Fragile X	Varies (includes 88285/88280/88261/88289)
Chromosome, Tissue	Varies (includes 88285 x3 /88280 x2 /88261 /88233 x2 /88239 x2)
CYP2D6 Gene Analysis	ARUP #51232 81226
Cystic Fibrosis Screening	81220
NEO EGFR Mutation	81235

GENETIC & MOLECULAR PRIOR AUTHORIZATION REQUIRED 2018	
Foundation One	81201/81206/81210/81211/81235/81242/81245/81270/81275/81292/81295/81298/81310/81315/81321
Hemochromatosis DNA	81256, 81257
Hemoglobin Conformation Newborn	83894
HLA ABC Luminex	81372
HLA B 27	81381, 81373, 81374
HLA DR DQ Lumnex	81376
HLA DQB Genotyping	81382 002
Huntington Disease	ARUP 40018 81401
IBD sgi Diagnostic - Prometheus	83520 / 82397 / 86140 / 88347 / 81479
IgH Heavy Chain by PCR	Varies, 81261
Jak 2, Qualitative	ARUP 51245 81402
Jak 2, Quantitative	ARUP 40168 81270
Jak 2 Exons 12-15	Mayo 89189 81403
Jak 2 Panel, with reflex to Exon 12	ARUP 2012085 81270 / reflex 81403
Jak 2 Panel, with reflex to CLAR with reflrx to MPL	ARUP 2012084 81270 / reflex 81479 / reflex 81402
KRAS	81275
Leiden Factor V by PCR	85307 / 81241
Lymphocyte Cell (T&B) Typing	Varies 88184 / 88185 x2 / 86355 / 86357 / 86357 / 86359 / 86360
MPL Gene Analysis	Varies ARUP 200545 81402
MTHFR Mutation Detection PCR	81291
Prothrombin Nucleotide 20210 (Factor II)	81240
T Cell Gene Rearrangement	81342
TPMT, Genetic	81401
CFTR Gene Full Sequence	81223
NEO KIT Gene Targeted Analysis	81272
NEO MLH1 Promoter Methylation	81288
NEO NRAS Gene Variants Exon 2&3	81311
FLT3 Mutation Detection	81245
Fragile X Mutation Analysis	81243
HLA B85701 Genotype	81381
IGHV Mutation Analysis	81263
NEO BRAF with KRAS	81275
KRAS Additional Variants	81276
NPM1 Gene	81310
PDGFRA Mutation Analysis	81314
PML RARA T 15,17, QUANTITIVE REAL TIME PCR	81315
SNRPN/UBE3A GENE	81331
STR MARKERS SPECIMEN ANAL	81265
TRB GENE REARRANGEAMPLIFY	81342
TRG GENE REARRANGEMENT ANAL	81342
TYROSINE KINASE DOMAIN TKD VARIANTS	81246
UGT1A1 GENE	81350

REFLEX TESTING

TEST ORDERED	CPT	REFLEX PROTOCOL	REFLEX CPT
Antibody Screen	86850	If positive, antibody identification (ABID), Antigen Typing (patient), Antigen Typing (units), Direct Coombs (DAT), Antibody Titer.	86870,86905, 86902, 86880, 86886
Direct Coombs (DAT)	86880	Eluate peformed when DAT is positive	86860
Rapid Strep Antigen (Group A)	87880	If negative, Strep Culture	87081
Acid Fast Culture	87116 and 87206, 87015 if indicated	Additional testing as needed	87077, 87118, 87149, 87181, 87184, 87186, 87188, 87190
Blood Culture	87040	Additional testing as needed	87077, 87147, 87181, 87184, 87185, 87186
Fungal Culture	87101, 87102, 87103, 87206	Additional testing as needed	87106, 87107
Routine Culture	87070 and 87075 for anaerobic culture if indicated and 87205 for gram stain. 87015 and 87176 if indicated	Additional testing as needed	87076, 87077, 87147, 87181, 87184, 87185, 87186
Stool Culture	87045, 87046, 87427	Additional testing as needed	87077, 87181, 87184, 87186
Urine Culture (includes Colony Count) Positive only	87086	Additional CPT's may be added for ID and susceptibility(ies)	87077, 87088, 87147, 87181, 87184, 87185, 87186
Clostrium Difficile	87324	Positive C. difficile EIA will reflex to C difficile PCR	87798
Trich Wet Prep	87210	If negative for Trichomonas, Trichomonas PCR will be performed	87661
ANA Antinuclear Antibody	86038	If positive or equivocal, ANA titer performed	86039
HIV	86703	If positive, Western Blot performed	86689
Hepatitis C Antibody	86803	If positive, additional testing as needed	87522
Syphilis Total Antibodies	86780	Reactive results will reflex to RPR. If RPR Negative will reflex to FTA-ABS. If FTA Inconclusive reflex to TP-PA.	86592, 86593
RPR	86592	If reactive will reflex to Syphilis Total Antibody	86780
Toxoplasma IgG	86777	If IgG positive, the toxplasma IgM will be performed	86778
Cryptococcus Antigen	86403	Positive results are titered	86406
Pediatric Respiratory Panel	87631	If Influenza A/B PCR and RSV PCR are both Negative, RVP PCR will be performed. CPT 87631 is credited if test is reflexed.	87633, 87798, 87486, 87581

TEST ORDERED	CPT	REFLEX PROTOCOL	REFLEX CPT
TSH/reflex to Free T4	84443	If TSH is abnormal, then FT4 is performed. If TSH is <0.10 and FT4 is normal, then FT3 is performed.	84439 84481
Transcutaneous Bilirubin	88720	If > 14.0 mg/dl, serum bili performed	82247
Protein Electrophoresis Serum Reflex to Immunofixation	84165	If Para protein present, ID by immunofixation electrophoresis	86334
Immunofixation Serum	86334	Protein electrophoresis Serum	84165
Drug screen, urine	80101x7 & G0431x7	Positive Amphetamine, methamphetamine screen confirmation is performed	82145
24 hour urine collections for any analyte	Examples: 82575, 82340, 84133	Urine volume is measured to determine 24-hr quantity of the analyte	81050
Urinalysis, Culture if Positive	81001	If urinalysis is positive culture is performed	87077, 87086, 87088, 87147, 87181, 87184, 87185, 87186
Lupus anticoagulent	85610, 85730, 85670, 85384	If PTT >44, mixing studies will be performed	85732, 85613x2
von Willebrand panel Reflex to Multimer	85240,85245, 85246	If abnormal von Willibrand Multimer performed.	85247
Activate Protein C Resistance Profile Reflex to Factor V Leiden PCR	85307	If positive Factor V Leiden PCR will be performed	81241
T and B lymphocytes	88184, 88185, 88185, 86355, 86357, 86359, 86360	CBC performed	85025
Cell surface markers	88184, multiples of 88185	CBC performed	85025
T4/T8 Ratio	86355, 86359	CD3, CBC performed	86359, 86360, 85025
BCR/ABL	83902, 83898x2, 83891, 83912	CBC performed	85025
Cytopathology fluids	88108, 88112, 88305, 88160, 88161	Per pathologist order	88312, 88313, 88318, 88319, 88342, 88346, 88182, 88184, 88185, 88187, 88188, 88189, 88329, 88333, 88334, 88348, 88349, 88360, 88361

TEST ORDERED	CPT	REFLEX PROTOCOL	REFLEX CPT
Pap smear, liquid fixative	88142, G0123	ASCUS r/o CIN or per pathologist order, HPV High Risk, HPV 16 and 18/45	87621
Peripheral Smear Consult	85060	CBC	85025
Surgical pathology	88300, 88302, 88304, 88305, 88307, 88309	Per pathologist order	88311, 88312, 88313, 88314, 88318, 88319, 88341, 88342, 88346, 88182, 88184, 88185, 88187, 88188, 88189, 88329, 88331, 88332, 88348, 88349, 88360, 88361, 88365, 88367, 88368
Chromosome Amniotic Fluid Rflx to FISH, Chromosome Blood Rflx to FISH, Chromosome Bone Marrow Rflx to FISH	88237, 88262, 88280, 88239,88261,88285	Per pathologist order, All require Pre Authorization, reflex to FISH	88237, 88271,88275
Tissue Culture; solid tumor	88239	Reflex to FISH	88237, 88271,88275
Chromosome analysis; count 5 cells, 1 karyotype, with banding	88261	Reflex to FISH	88237, 88271,88275
Chromosome analysis; additional cells counted, each study	88285	Reflex to FISH	88237, 88271,88275