MedStar Family Choice

ADMINISTRATIVE POLICY AND PROCEDURE		
Policy #:	**1427**	
Subject:	**Non-Invasive Prenatal Aneuploidy and Other Prenatal Genetic Testing**	
Section:	**Medical Non-Pharmacy Protocols**	
Initial Effective Date:	**12/03/2020**	
Revision Effective Date(s):	**07/21, 07/22, 07/23, 07/24**	
Review Effective Date(s):		
Responsible Parties:	**Medical Director**	
Responsible Department(s):	**Clinical Operations**	
Regulatory References:	**MDH Policy Non-Invasive Prenatal Testing (NIPTs) Clinical Criteria (12/20/20) and Non-Invasive Prenatal Testing (NIPTs) Ordering Guidelines; MDH Whole Exome Sequencing (WES) Clinical Criteria**	
Approved:	**AVP Clinical Operations**	**Chief Medical Officer**

Purpose: **To define the conditions under which MedStar Family Choice (MFC) will provide Non-Invasive Prenatal Aneuploidy Testing and other prenatal genetic testing for screening.**

Scope: **MedStar Family Choice, Maryland**

Policy: **It is the policy of MFC to offer non-invasive prenatal screening testing without authorization for trisomy 13, 18 and 21 in accordance with MDH and ACOG recommendations. Testing beyond these screening tests will require prior authorization.**

Procedure:

Basic Screening:

1. Prenatal screening for fetal aneuploidy will be available for all pregnant women without prior authorization starting at 10 weeks gestational age for **singleton pregnancy only**.
2. First Trimester Screening should include an ultrasound and aneuploidy screening OR traditional Quad screening but NOT both. Ultrasound with NIPTs is the preferred method.
3. LabCorp and Myriad are MedStar Family Choice's contracted laboratories. OB GYN providers must send samples to one of these laboratories.

4. For LabCorp, the **only** test ordered should be "**MaterniT21 PLUS Core + SCA**". It is **LabCorp test #451934** and it will report aneuploidy for chromosome 21, 18 and 13, sex chromosome aneuploidy (Turner syndrome, Klinefelter syndrome, etc.) and sex of the baby. If this **EXACT** test is ordered, no prior authorization will be required. Any other test will require prior authorization.
5. For Myriad, on their order form under *Myriad Prequel Prenatal Screen -Noninvasive prenatal screen,* check the box for *Common aneuploidy, chromosome 13, 18, 21* AND check the box next to *Include sex chromosome analysis*. If these two boxes are checked, no prior authorization will be required. Any other test will require prior authorization. (see Myriad Order Form inserted below)
6. Second Trimester Screening should still include a detailed anatomic ultrasound and an alfa fetal protein level.

Advanced Testing:

Further genetic testing will require prior authorization and must be ordered by a Maternal Fetal Medicine Specialist or after consultation with a Genetic Counselor. Further testing will be considered when fetal ultrasound findings show anatomic abnormalities.

1. Requests must be submitted with evidence of consultation with a Maternal Fetal Medicine Specialist or a Genetic Counselor.
2. The medical records submitted must indicate the reason for the request, the condition suspected and the anticipated actions or change of clinical management to be taken based on the outcome of the testing.
3. For LabCorp, the specific testing requested would be **MaterniT21 Genome Add On (LabCorp test # 452104 or 452114** if redraw needed) which would return a "comprehensive chromosome copy number analysis including unbalanced derivatives, and information about deletions or duplications of chromosome material 7 Mb or larger, as well as analysis of seven clinically relevant microdeletions less than 7 Mb in size." Any other version of the LabCorp MaterniT21 tests would duplicate the original screening test and is thus not medically necessary.
4. For Myriad, on their order form check ONLY the box next to *microdeletions, singleton only* (see Myriad Order Form inserted below)
5. Any other genetic testing will require consultation with Maternal Fetal Medicine or Genetic Counselor and documentation as in 2. above.

Excluded From Coverage:

Per MDH NIPTs Clinical Criteria document the following are excluded from coverage:

1. Testing as a follow-up to an abnormal 1st or 2nd trimester screening
2. Low Fetal Fraction on initial NIPTs testing (counseling and diagnostic testing recommended)
3. Cases with a known co-twin demise (vanishing twin syndrome)
4. Screening for trisomies other than 21, 18, and 13
5. Screening for single-gene disorders
6. Whole genome NIPTs
7. Whole exome sequencing

8. When used to determine genetic cause of miscarriage or fetal demise (e.g., missed abortion, incomplete abortion)

Out of Network Testing:

1. All requests for out of network laboratories will require prior authorization and will only be approved if the testing is not available from an in-network laboratory and is determined to be medically necessary.

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Per the MDH policy

CPT 81420 (Fetal chromosomal aneuploidy (e.g., trisomy **21**, monosomy X) genomic sequence analysis panel, circulating cell- free fetal DNA in maternal blood, must include analysis of chromosomes **13**, **18**, and **21**) - no PA for Prenatal testing
CPT 81507 (Fetal aneuploidy (trisomy **21**, **18**, and **13**) DNA sequence analysis of selected regions using maternal plasma, algorithm reported as a risk score for each trisomy) - no PA for Prenatal testing
CPT 81422 (Fetal chromosomal microdeletion(s) genomic sequence analysis (e.g., DiGeorge syndrome, Cri-du-chat syndrome), circulating cell-free fetal DNA in maternal blood) - PA required
CPT 81479 (Unlisted molecular pathology procedure)– PA required (this CPT may only be used for NIPTs testing)

References: Content created in conjunction with MSH OBGYN Clinical Practice Council.

Attachments:
Attachment A – Myriad Order Form

Summary of Changes:	**07/24:** • Removed specific names for "Responsible Parties" and "Approved"; just using titles • Added WES exclusion as per MDH WES Clinical Criteria **07/23:** • Updated approved by to Carol Attia and Dr. Wills • Clarified when advanced testing will be considered • Added exclusions as per MDH **07/22:** • Added Attachment A - Myriad Order Form. **07/21:** • Updated Responsible Departments from Utilization Management to Clinical Operations. **12/20:** • New policy.

Attachment A

FORESIGHT | PREQUEL

REQUISITION FORM

for Foresight Carrier Screen and Prequel Prenatal Screen

1. At a minimum, the patient's name, DOB and address must be included on this requisition (even if the patient's name is included elsewhere). Not doing so will result in sample delays.

2. Please note that if more than one ethnicity is selected, race will be reported as Other/ Mixed Caucasian, unless Ashkenazi Jewish has been selected. If no ethnicity is selected, Northern European will be reported.

3. If selecting this option, please ensure that the insurance carrier information is filled out, even if a copy of the insurance card is included. Please do not fill out this information if the patient is selecting Option B or C.

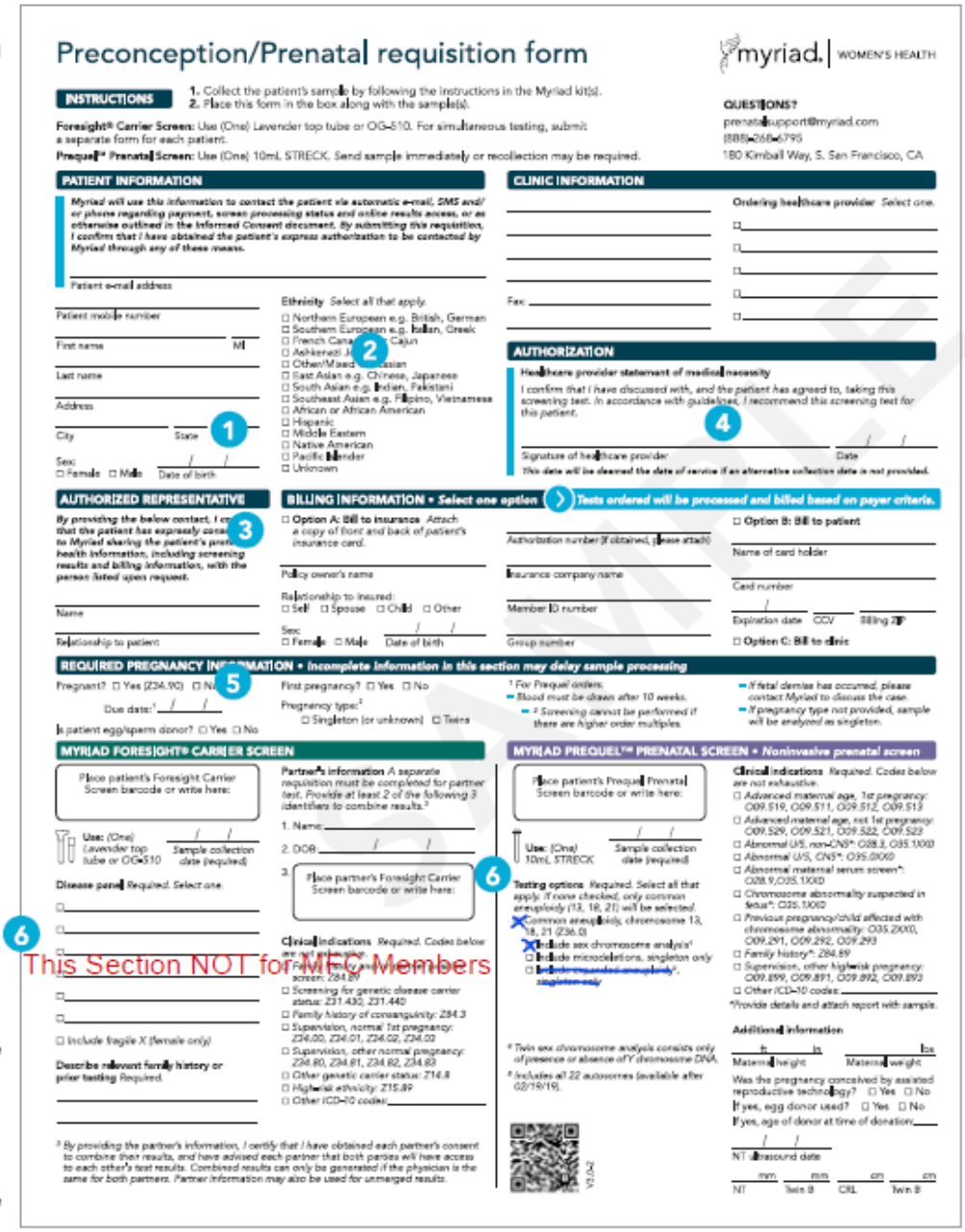
4. Please make sure to date and sign this form.

5. Indicate whether the patient is pregnant at the time of testing.

6. Please fill this in. Clinical information is necessary and missing information can result in sample delays. If marking a code with an asterisk, please provide more information (reports, clinical data, etc.).

- Some insurers may require additional paperwork. Please contact your clinic's account executive for information on relevant forms or with any questions.

- When merging orders for a couple: 1) A separate requisition form must be filled out in its entirety for the partner, 2) The [illegible] must be the same for both patients, 3) Results will not be released until both partners results have been completed.



Preconception/Prenatal requisition form

myriad. | WOMEN'S HEALTH

INSTRUCTIONS
1. Collect the patient's sample by following the instructions in the Myriad kit(s).
2. Place this form in the box along with the sample(s).

Foresight® Carrier Screen: Use (One) Lavender top tube or OG-510. For simultaneous testing, submit a separate form for each patient.
Prequel™ Prenatal Screen: Use (One) 10mL STRECK. Send sample immediately or recollection may be required.

QUESTIONS?
prenatalsupport@myriad.com
(888)-268-6795
180 Kimball Way, S. San Francisco, CA

PATIENT INFORMATION
Myriad will use this information to contact the patient via automatic e-mail, SMS and/ or phone regarding payment, screen processing status and online results access, or as otherwise outlined in the Informed Consent document. By submitting this requisition, I confirm that I have obtained the patient's express authorization to be contacted by Myriad through any of these means.
Patient e-mail address
Patient mobile number
First name MI
Last name
Address
City State
Sex: ☐ Female ☐ Male Date of birth
Ethnicity Select all that apply.
☐ Northern European e.g. British, German
☐ Southern European e.g. Italian, Greek
☐ French Canadian ☐ Cajun
☐ Ashkenazi Jewish
☐ Other/Mixed Caucasian
☐ East Asian e.g. Chinese, Japanese
☐ South Asian e.g. Indian, Pakistani
☐ Southeast Asian e.g. Filipino, Vietnamese
☐ African or African American
☐ Hispanic
☐ Middle Eastern
☐ Native American
☐ Pacific Islander
☐ Unknown

CLINIC INFORMATION
Ordering healthcare provider Select one.
Fax:

AUTHORIZATION
Healthcare provider statement of medical necessity
I confirm that I have discussed with, and the patient has agreed to, taking this screening test. In accordance with guidelines, I recommend this screening test for this patient.
Signature of healthcare provider Date
This date will be deemed the date of service if an alternative collection date is not provided.

AUTHORIZED REPRESENTATIVE
By providing the below contact, I confirm that the patient has expressly consented to Myriad sharing the patient's protected health information, including screening results and billing information, with the person listed upon request.
Name
Relationship to patient

BILLING INFORMATION • Select one option
Tests ordered will be processed and billed based on payer criteria.
☐ Option A: Bill to insurance Attach a copy of front and back of patient's insurance card.
Policy owner's name
Relationship to insured: ☐ Self ☐ Spouse ☐ Child ☐ Other
Sex: ☐ Female ☐ Male Date of birth
Authorization number (if obtained, please attach)
Insurance company name
Member ID number
Group number
☐ Option B: Bill to patient
Name of card holder
Card number
Expiration date CCV Billing ZIP
☐ Option C: Bill to clinic

REQUIRED PREGNANCY INFORMATION • Incomplete information in this section may delay sample processing
Pregnant? ☐ Yes (Z34.90) ☐ No
Due date:[1]
Is patient egg/sperm donor? ☐ Yes ☐ No
First pregnancy? ☐ Yes ☐ No
Pregnancy type:[2]
☐ Singleton (or unknown) ☐ Twins
[1] For Prequel orders: Blood must be drawn after 10 weeks.
[2] Screening cannot be performed if there are higher order multiples.
If fetal demise has occurred, please contact Myriad to discuss the case.
If pregnancy type not provided, sample will be analyzed as singleton.

MYRIAD FORESIGHT® CARRIER SCREEN
Place patient's Foresight Carrier Screen barcode or write here:
Use: (One) Lavender top tube or OG-510
Sample collection date (required)
Disease panel Required. Select one.
☐
☐
☐
☐ Include fragile X (female only)
Describe relevant family history or prior testing Required.
Partner's information A separate requisition must be completed for partner test. Provide at least 2 of the following 3 identifiers to combine results.[3]
1. Name:
2. DOB
3. Place partner's Foresight Carrier Screen barcode or write here:
Clinical indications Required. Codes below are not exhaustive.
☐ Foresight carrier screen: Z84.89
☐ Screening for genetic disease carrier status: Z31.430, Z31.440
☐ Family history of consanguinity: Z84.3
☐ Supervision, normal 1st pregnancy: Z34.00, Z34.01, Z34.02, Z34.03
☐ Supervision, other normal pregnancy: Z34.80, Z34.81, Z34.82, Z34.83
☐ Other genetic carrier status: Z14.8
☐ High-risk ethnicity: Z15.89
☐ Other ICD-10 codes:
[3] By providing the partner's information, I certify that I have obtained each partner's consent to combine their results, and have advised each partner that both parties will have access to each other's test results. Combined results can only be generated if the physician is the same for both partners. Partner information may also be used for unmerged results.

MYRIAD PREQUEL™ PRENATAL SCREEN • Noninvasive prenatal screen
Place patient's Prequel Prenatal Screen barcode or write here:
Use: (One) 10mL STRECK
Sample collection date (required)
Testing options Required. Select all that apply. If none checked, only common aneuploidy (13, 18, 21) will be selected.
☒ Common aneuploidy, chromosome 13, 18, 21 (Z36.0)
☐ Include sex chromosome analysis[4]
☐ Include microdeletions, singleton only
☐ Include rare autosomal aneuploidy[5], singleton only
[4] Twin sex chromosome analysis consists only of presence or absence of Y chromosome DNA.
[5] Includes all 22 autosomes (available after 03/19/19).
Clinical indications Required. Codes below are not exhaustive.
☐ Advanced maternal age, 1st pregnancy: O09.519, O09.511, O09.512, O09.513
☐ Advanced maternal age, not 1st pregnancy: O09.529, O09.521, O09.522, O09.523
☐ Abnormal U/S, non-CNS*: O28.3, O35.1X00
☐ Abnormal U/S, CNS*: O35.0X00
☐ Abnormal maternal serum screen*: O28.9,O35.1X00
☐ Chromosome abnormality suspected in fetus*: O35.1X00
☐ Previous pregnancy/child affected with chromosome abnormality: O35.2X00, O09.291, O09.292, O09.293
☐ Family history*: Z84.89
☐ Supervision, other high-risk pregnancy: O09.899, O09.891, O09.892, O09.893
☐ Other ICD-10 codes:
*Provide details and attach report with sample.
Additional information
ft in Maternal height
lbs Maternal weight
Was the pregnancy conceived by assisted reproductive technology? ☐ Yes ☐ No
If yes, egg donor used? ☐ Yes ☐ No
If yes, age of donor at time of donation:
NT ultrasound date
mm NT mm Twin B cm CRL cm Twin B

V3.0A2

6 This Section NOT for MFC Members

Not for MFC Members

NOT for MFC Members

- When ordering both Prequel and Foresight for a couple, please note that **three** samples and **two** test requisitions are required. Both tests can be ordered using samples for the female patient (saliva or 4ml blood and 10ml blood) and **one** requisition and **one** sample for her partner (saliva or 4ml blood). For ease of use, all samples can be sent in one FedEx envelope.