August 12, 2022

Chiquita Brooks-LaSure, Administrator
Centers for Medicare & Medicaid Services
7500 Security Blvd., Baltimore, MD 21224

Subject: Call for Public Comment – Calendar Year 2023 Physician Fee Schedule

Dear Administrator Brooks-LaSure,

The National Society of Genetic Counselors (NSGC) would like to thank the Centers for Medicare & Medicaid Services (CMS) for the opportunity to comment on the proposed changes outlined in the Calendar Year 2023 Payment Policies under the Physician Fee Schedule.

NSGC advocates for the professional interests of genetic counselors and manages a network for professional communications, offering publications, clinical guidelines, education, and other genetic counseling resources. Given the increasing incidence of conditions associated with a genetic component impacting risk, such as cancer, dementia, and cardiovascular disease, there is a need for genetic services to assess a patient's risk and inform treatment-making decisions. Genetic counselors receive specialized training in both medical genetics and counseling and are instrumental in the accurate interpretation of genetic tests and provision of critical guidance to patients.

In 2021, NSGC submitted an Improvement Activity (IA) titled *Improve Access to Genetic Counseling and Testing* for consideration in the Medicare Quality Payment Program (QPP) Merit-based Incentive Payment System (MIPS) in response to CMS' Call for Measures and Activities. This IA is intended to drive appropriate engagement between eligible clinicians and genetic counselors. It also seeks to improve Medicare beneficiaries' experience and health outcomes by integration of genetic counselors into clinical care teams and establishing protocols to increase access to genetic services in appropriate scenarios.

The genetic counseling IA:

- Meets all eight Improvement Activity acceptance criteria
- Aligns with CMS's Framework for Health Equity and promotes health equity for vulnerable patients where genetic factors contribute to healthcare disparities
- Promotes comprehensive screening and early detection for colorectal cancer (CRC), which can in turn address racial and ethnic disparities among vulnerable at-risk populations
- Aligns with and supports the quality goals of proposed MIPS Value Pathways (MVPs) for cancer, neurological and neurodegenerative diseases, and kidney disease
- Creates an incentive to improve appropriate access to care in the absence of quality measures that directly assess genetic counseling services and outcomes, and bolsters proposed quality measures that are relevant but indirectly related to genetic counseling (e.g., MMR/MSI testing) by driving coordination between physicians and genetic counselors

For these reasons, explored in greater detail below, we request that CMS consider inclusion of the *Improve Access to Genetic Counseling and Testing* IA in the MIPS IA Inventory for Performance Year 2023 or future years. Alternatively, we would request that, if CMS has determined that the genetic counseling IA overlaps with existing activities in the MIPS IA Inventory, that the proposed interventions be reflected in the current validation criteria to ensure that clinicians can earn credit for those IAs by promoting improved access to genetic counseling.

While CMS did not propose the genetic counseling IA in this rulemaking cycle, we believe that the activity advances CMS' goals for value-based care by improving the quality of patient outcomes and driving cost efficiency in genetic test selection. Below, we summarize NSGC's key takeaways regarding the genetic counseling IA's value in the QPP and its alignment with policies described in the CY2023 proposed Physician Fee Schedule rule.

Rationale:

Genetic Counseling IA Meets Acceptance Criteria

The MIPS Call for Improvement Activities requires that proposed IA concepts meet all eight of CMS' acceptance criteria. The genetic counseling IA is designed to be broadly applicable across multiple clinical areas serviced by Medicare clinicians and is informed by evidence-based interventions that drive quality in care. Below, we have provided rationale reaffirming that the IA meets CMS' acceptance criteria:

- *(#1): Relevance to an existing improvement activity's subcategory (or a proposed new subcategory):* Care coordination involves the organization of patient care services and information sharing among all members of the patient care team to achieve safer and more effective care.[1] The genetic counseling IA requires attesting clinicians to demonstrate that 1) genetic counselors have been integrated into multidisciplinary care teams to expand patient access to genetic counseling, 2) that referral trigger processes have been implemented, or 3) that processes to improve identification of patients appropriate for genetic counseling and testing are in place, which enhance communication and care coordination between referring providers and the genetic counselor.

- *(#2): Importance of an activity toward achieving improved beneficiary health outcomes* and *(#3): Evidence supports that an activity has a high probability of contributing to improved beneficiary health outcomes:* Genetic risks may affect any individual at any age. Because risks are generally cumulative throughout one's lifetime, there is a higher incidence in older adult populations for conditions that can have a genetic predisposition such as cancer, cardiovascular disease, and neurological conditions. Evidence-based guidelines for conditions prevalent in the older adult population, including the National Comprehensive Cancer Network (NCCN) Guidelines for Genetic/Familial High-Risk Assessment: Breast, Ovarian, and Pancreatic Cancer and NSGC's joint guidelines with the American Society of Breast Surgeons, recommend that all individuals with these cancers should be offered genetic counseling and germline testing or evaluation for hereditary risk of cancer for patients with breast cancer.[2,3] Despite these recommendations, gaps in actual delivery of genetic services remain. A review of the literature assessing opportunities for prevention of ovarian cancer indicate that referral rates for genetic counseling and subsequent *BRCA1/2* testing are low, ranging from 10-30%, despite therapeutic benefits for patients who

[1] Agency for Healthcare Research and Quality. Care Coordination. Reviewed August 2018. https://www.ahrq.gov/ncepcr/care/coordination.html.

[2] Daly, M. B., Pal, T., Berry, M. P., Buys, S. S., Dickson, P., Domchek, S. M., Elkhanany, A., Friedman, S., Goggins, M., Hutton, M. L., CGC, Karlan, B. Y., Khan, S., Klein, C., Kohlmann, W., CGC, Kurian, A. W., Laronga, C., Litton, J. K., Mak, J. S., Dwyer, M. A. (2021). Genetic/Familial High-Risk Assessment: Breast, Ovarian, and Pancreatic, Version 2.2021, NCCN Clinical Practice Guidelines in Oncology. Journal of the National Comprehensive Cancer Network: JNCCN, 19(1), 77–102. https://doi.org/10.6004/jnccn.2021.0001.

[3] ASBrS-NSGC Joint Statement of Medical Societies Regarding Genetic Testing Requirements. American Society of Breast Surgeons and National Society of Genetic Counselors. 2021. https://www.breastsurgeons.org/docs/news/2021_ASBrS_NSGC_Joint_Statement.pdf.

carry high-risk *BRCA1/2* genetic susceptibility.[4] Interventions provided in the genetic counseling IA can help to identify and stratify risks to inform frequency of surveillance for early detection and inform risk-reduction measures for these cancer types. Integration of a board-certified genetic counselor within an existing care team has been shown to decrease the length of time between referral and genetic counseling consultation.[5] Genetic counselors' focus on patient care is to deliver accurate health information to patients in a way that they can understand, and support patients to make healthcare-related decisions that best fit their wants and needs.[6] Individuals who feel confident and empowered to make informed healthcare decisions are more likely to be involved in and follow through on their care plan.[7] Genetic counseling has been shown to improve patient psychological outcomes, including reduced decisional regret, and increased self-efficacy, empowerment and family communication, as well as the potential to impact overall health outcomes, as a result of more accurate interpretation of test results and closer collaboration with physicians. The following studies demonstrate the importance of increased access to genetic counseling, as laid out in the proposed IA to improve beneficiary outcomes:

- One systematic review evaluated studies that assessed pre- and post-interventions with genetic counselors and found that genetic counseling can improve psychosocial measures (i.e., knowledge, perceived personal control, anxiety, cancer-related worries, and decisional conflict) in addition to improving positive health behaviors.[8]
- For patients undergoing cardiovascular genetic counseling, mean patient empowerment scores after counseling increased by 17.5 points, and individual awareness of surveillance recommendations for at-risk family members increased by 76%.[9,10] Facilitating identification of at-risk family members and providing early-detection and risk-reduction recommendations for them is a unique contribution of genetic counselors to healthcare and enables wider reaching health outcomes.
- One large population-level study observed that surgeons managed patients with a *BRCA1/2* pathogenic variant the same as patients whose test results were a variant of uncertain significance (VUS), based on their misunderstanding of how to interpret this genetic result and that half of the average-risk patients with VUS underwent bilateral

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[4] Katz, S. J., Ward, K. C., Hamilton, A. S., Mcleod, M. C., Wallner, L. P., Morrow, M., Jagsi, R., Hawley, S. T., & Kurian, A. W. (2018). Gaps in Receipt of Clinically Indicated Genetic Counseling After Diagnosis of Breast Cancer. Journal of clinical oncology : official journal of the American Society of Clinical Oncology, 36(12), 1218–1224. https://doi.org/10.1200/JCO.2017.76.2369.

[5] Senter L, O'Malley D, Backes F, Copeland L, Fowler J, Salani R, et al. Change in genetics service model increases ovarian cancer patient referrals and decreases time to consultation: Improving compliance with guideline-based quality care. Gynecologic Oncology 2017 Jun;145:165-166. https://linkinghub.elsevier.com/retrieve/pii/S0090825817305966.

[6] "Genetic Counseling." Office of Science (OS), Office of Genomics and Precision Public Health. Centers for Disease Control & Prevention. https://www.cdc.gov/genomics/gtesting/genetic_counseling.htm

7 Bailo, L., Guiddi, P., Vergani, L., Marton, G., & Pravettoni, G. (2019). The patient perspective: investigating patient empowerment enablers and barriers within the oncological care process. E Cancer Medical Science, 13, 912. https://doi.org/10.3332/ecancer.2019.912.

[8] Madlensky L, Trepanier AM, Cragun D, et al. A Rapid Systematic Review of Outcomes Studies in Genetic Counseling. *J Genet Couns*. 2017;26(3):361-378. https://pubmed.ncbi.nlm.nih.gov/28168332/.

[9] Ison, H. E., Ware, S. M., Schwantes-An, T. H., Freeze, S., Elmore, L., & Spoonamore, K. G. (2019). The impact of cardiovascular genetic counseling on patient empowerment. Journal of genetic counseling, 28(3), 570–577. https://doi.org/10.1002/jgc4.1050.

[10] Murray, B., Tichnell, C., Burch, A. E., Calkins, H., & James, C. A. (2022). Strength of the genetic counselor: patient relationship is associated with extent of increased empowerment in patients with arrhythmogenic cardiomyopathy. Journal of genetic counseling, 31(2), 388–397. https://doi.org/10.1002/jgc4.1499.

mastectomy, an invasive procedure that may have been unnecessary for these individuals.[11]

- *(#4): Feasible to implement recognizing importance in minimizing burden, including, to the extent possible, for small practices, practices in rural areas, or practices in areas designated as geographic HPSAs by the Health Resources and Services Administration:* The level of effort to implement the genetic counseling IA is dependent on resources available to clinicians at their practice or institution. However, the activity was designed to minimize provider burden, recognizing the potential strain on staff resources. The activity requires regular access to genetic counselors but highlights the importance of low-burden interventions such as improving referral processes or establishing standardized protocols that will streamline future workflow processes. Use of telehealth modalities may also increase practice access to board-certified genetic counselor services.[12] The interventions in the IA, such as integrating genetic counselors into multidisciplinary care teams to assess implications of test results for patients (e.g., heritable conditions leading to cancer such as Lynch Syndrome), may also reduce practice burden in reporting MIPS quality measures, including the proposed *Mismatch Repair (MMR) or Microsatellite Instability (MSI) Biomarker Testing Status in Colorectal Carcinoma, Endometrial, Gastroesophageal, or Small Bowel Carcinoma*.

- *(#5): Can be linked to existing and related MIPS quality, Promoting Interoperability, and cost measures as applicable and feasible:* The interventions included within the genetic counseling IA can support multiple current and proposed MIPS measures across several domains. While these measures do not directly assess genetic counseling services, they do assess areas of screening, diagnostics, and treatment decision-making where appropriate integration of genetic counselors can improve the quality of care:
    - **Patient Experience:** CAHPS for MIPS Clinician/Group Survey (#321); Person-Centered Primary Care Measure Patient Reported Outcome Performance Measure (PCPCM PRO-PM) (#483)
    - **Cancer Screening:** Age-Appropriate Screening Colonoscopy (#439); Breast Cancer Screening (#111); Colorectal Cancer Screening (#113); Mismatch Repair (MMR) or Microsatellite Instability (MSI) Biomarker Testing Status in Colorectal Carcinoma, Endometrial, Gastroesophageal, or Small Bowel Carcinoma (proposed)
    - **Neurological:** Dementia Associated Behavioral and Psychiatric Symptoms Screening and Management (#283)
    - **Prenatal/Postpartum Care:** Maternity Care: Postpartum Follow-Up and Care Coordination (#336); Epilepsy: Counseling for Women of Childbearing Potential with Epilepsy (#268)
    - Furthermore, increased access to genetic counseling can impact overall cost outcomes, measured through the Total Cost of Care and Medicare Spending Per Beneficiary Cost category measures. For example, modified testing after genetic counselor review has been shown to result in a cost-savings of $98,750.64, or an average of $2,015.32 per modification.[13]

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[11] Kurian AW, Li Y, Hamilton AS, et al. Gaps in Incorporating Germline Genetic Testing Into Treatment Decision-Making for Early-Stage Breast Cancer. *J Clin Oncol.* 2017;35(20):2232-2239. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5501363/.

[12] Cacioppo, C. N., Egleston, B. L., Fetzer, D., Burke Sands, C., Raza, S. A., Reddy Malleda, N., McCarty Wood, E., Rittenburg, I., Childs, J., Cho, D., Hosford, M., Khair, T., Khatri, J., Komarnicky, L., Poretta, T., Rahman, F., Shah, S., Patrick-Miller, L. J., Domchek, S. M., & Bradbury, A. R. (2021). Randomized study of remote telehealth genetic services versus usual care in oncology practices without genetic counselors. Cancer medicine, 10(13), 4532–4541. https://doi.org/10.1002/cam4.3968.

[13] Wakefield, E., Keller, H., Mianzo, H., Nagaraj, C. B., Tawde, S., & Ulm, E. (2018). Reduction of Health Care Costs and Improved Appropriateness of Incoming Test Orders: the Impact of Genetic Counselor Review in an

- *(#6): CMS is able to validate the activity:* The proposed IA includes documentation requirements that CMS can use to validate adoption of specific interventions. Clinicians can submit documentation of genetic counselor services, such as placing a referral, in addition to other protocol evidence, reports of genetic test ordering, and educational intervention documentation.

- *(#7): Does not duplicate other improvement activities in the Inventory:* We identified access to genetic counseling as a gap and developed the IA with specific attention to provide interventions not included in other adopted IAs in the inventory. While some IAs in the inventory address care coordination, none of the activities address increasing access to genetic counselors through specific multidisciplinary care teams, universal testing protocols for appropriate clinical scenarios, or implementation of protocols to trigger genetic counseling referrals or improve identification of eligible patients for referrals.

- *(#8): Should drive improvements that go beyond purely common clinical practices:* Numerous clinical guidelines for hereditary cancer, prenatal or preconception testing, and cardiac conditions recommend genetic counseling as part of standard practice for risk assessment and initial evaluation. Additionally, access to genetic counselors are required for many accreditation programs such as Commission on Cancer, and the National Association of Professional Breast Centers (NAPBC).[14] However, patients may be prevented from routinely accessing care, due to primary care providers' limited knowledge of the implications of genetic testing, ability to access care, and availability of genetic counselors. [15,16,17,18] These factors justify the need for evidence-based interventions that expand access to genetic counseling. The genetic counseling IA is intended to drive practice improvements by streamlining access to genetic counseling through improved integration with multidisciplinary care teams and establishing referral triggers and enhancing communication and collaboration between physicians and genetic counselors.

Genetic Counseling IA Promotes Health Equity

The activities implemented under the proposed genetic counseling IA would address healthcare disparities, and align with several priorities of CMS's Framework for Health Equity:

- *Build capacity of health care organizations and the workforce to reduce health and health care disparities:* Evidence suggests that disparities in genetic counseling and testing may be due in part to inability of providers and care teams to identify patients who would benefit from these services. For example, Black women are less likely to undergo *BRCA1/2* testing and other multi-

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Academic Genetic Testing Laboratory. Journal of genetic counseling, 27(5), 1067–1073. https://doi.org/10.1007/s10897-018-0226-8.

[14] National Accreditation Program For Breast Centers Standards Manual. 2018. www.facs.org/media/pofgxojm/napbc_standards_manual_2018.pdf.

[15] Konstantinopoulos, P. A., Norquist, B., Lacchetti, C., Armstrong, D., Grisham, R. N., Goodfellow, P. J., Kohn, E. C., Levine, D. A., Liu, J. F., Lu, K. H., Sparacio, D., & Annunziata, C. M. (2020). Germline and Somatic Tumor Testing in Epithelial Ovarian Cancer: ASCO Guideline. Journal of clinical oncology : official journal of the American Society of Clinical Oncology, 38(11), 1222–1245. https://doi.org/10.1200/JCO.19.02960.

[16] Ahmad, F., McNally, E. M., Ackerman, M. J., Baty, L. C., Day, S. M., Kullo, I. J., Madueme, P. C., Maron, M. S., Martinez, M. W., Salberg, L., Taylor, M. R., & Wilcox, J. E. (2019). Establishment of Specialized Clinical Cardiovascular Genetics Programs: Recognizing the Need and Meeting Standards: A Scientific Statement From the American Heart Association. Circulation. Genomic and precision medicine, 12(6), e000054.

[17] Chou, A. F., Duncan, A. R., Hallford, G., Kelley, D. M., & Dean, L. W. (2021). Barriers and strategies to integrate medical genetics and primary care in underserved populations: a scoping review. Journal of community genetics, 12(3), 291–309. https://doi.org/10.1007/s12687-021-00508-5.

[18] Reid, S., Spalluto, L. B., Lang, K., Weidner, A., & Pal, T. (2022). An overview of genetic services delivery for hereditary breast cancer. Breast cancer research and treatment, 191(3), 491–500. https://doi.org/10.1007/s10549-021-06478-z.

panel genetic testing than White women, despite a higher incidence of early-onset and triple-negative breast cancer (both indications for genetic evaluation and testing).[19] The genetic counseling IA includes practice improvements that would build the capacity of the workforce to address disparities, such as development of standard protocols (e.g., integration of evidence-based tools for family history built into EHR platforms) to trigger a referral for genetic counseling if a patient's family or medical history indicates a suspected genetic condition. Other interventions, such as referral triggers, not only streamline and improve workflow and empower the workforce to increase capacity of practices to deliver quality care, but they can also reduce disparities in patients who receive genetic services and enhance health outcomes.

- *Advance language access, health literacy, and the provision of culturally tailored services:* One study of Spanish-speaking populations indicated that verbal/written communication problems, including limited availability and inadequate interpretation services during clinic visits prevented them from seeking relevant genetic services.[20] The genetic counseling IA promotes the use of educational materials and patient-focused interventions to increase patient awareness of the importance of genetic counseling services, which may include culturally and linguistically-appropriate materials.

Genetic Counseling IA Promotes Comprehensive Screening and Early Detection for Colorectal Cancer (CRC)

- CMS is proposing that a follow-up colonoscopy to an at-home test be considered a preventive service rather than strictly diagnostic. Further, CMS proposes to reduce the minimum age for payment for these services, meaning that the cost of follow-up colonoscopy would be covered by Medicare for patients ≥45 years of age, in alignment with new USPSTF guidelines. This proposal is intended to increase colonoscopy-only referral completion rates and address health disparities. While CRC rates affect non-White populations at disproportionally higher rates, social drivers exacerbate existing genetic susceptibility. Black and Hispanic patients are 26% and 34% less likely, respectively, than White populations to receive CRC screening recommendations from providers. Socioeconomic factors (e.g., education, income, access to care), as well as systemic racism, continue to perpetuate inequities in CRC screening.[21,22] This is concerning as Black Americans have higher incidence and mortality from CRC than any other groups in the US, with some carrying genetic variants that cause Lynch Syndrome-related increased risk of CRC in an environment where they may already be disproportionally affected by CRC risk.[23] Because Lynch Syndrome requires intensive surveillance and management of other associated cancer risks (e.g., uterine cancer), increasing access to genetic counselors can improve early identification of high-risk individuals and facilitate potentially life-saving cascade testing to family members.[24]

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[19] Jones, T., McCarthy, A. M., Kim, Y., & Armstrong, K. (2017). Predictors of BRCA1/2 genetic testing among Black women with breast cancer: a population-based study. Cancer medicine, 6(7), 1787–1798. https://doi.org/10.1002/cam4.1120.

[20] Gene Hallford, H., Coffman, M. A., Obregon-Tito, A. J., Morales, A. H., & Williamson Dean, L. (2020). Access barriers to genetic services for Spanish-speaking families in states with rapidly growing migrant populations. Journal of genetic counseling, 29(3), 365–380. https://doi.org/10.1002/jgc4.1195.

[21] Ahmed, N. U., Pelletier, V., Winter, K., & Albatineh, A. N. (2013). Factors explaining racial/ethnic disparities in rates of physician recommendation for colorectal cancer screening. American journal of public health, 103(7), e91–e99. https://doi.org/10.2105/AJPH.2012.301034.

[22] White, P. M., & Itzkowitz, S. H. (2020). Barriers Driving Racial Disparities in Colorectal Cancer Screening in African Americans. Current gastroenterology reports, 22(8), 41. https://doi.org/10.1007/s11894-020-00776-0.

[23] May, F. P., Almario, C. V., Ponce, N., & Spiegel, B. M. (2015). Racial minorities are more likely than whites to report lack of provider recommendation for colon cancer screening. The American journal of gastroenterology, 110(10), 1388–1394. https://doi.org/10.1038/ajg.2015.138.

[24] Pearlman, R., Frankel, W. L., Swanson, B. J., Jones, D., Zhao, W., Yilmaz, A., Miller, K., Bacher, J., Bigley, C., Nelsen, L., Goodfellow, P. J., Goldberg, R. M., Paskett, E., Shields, P. G., Freudenheim, J. L., Stanich, P. P.,

Interventions within the genetic counseling IA, such as establishment of universal testing protocols for appropriate clinical scenarios (e.g., family history of CRC), or standardized processes to improve identification of eligible patients for genetic services, would incentivize providers and practices to coordinate care with genetic counselors.

Genetic Counseling IA Addresses a Lack of Measures Directly Assessing Genetic Counseling Services and Supplements Proposed Indirectly-Relevant Quality Measures

- While there are quality measures that are relevant to conditions associated with a genetic variance, there are currently no quality measures that directly assess genetic counseling services or outcomes across key patient care continuum domains (i.e., initial screening, risk evaluation, assessment, and genetic testing process). In the absence of such measures, which would assess processes and outcomes associated with genetic counseling services, the genetic counseling IA can create a critical incentive in the QPP for providers to improve access to genetic counseling services. This IA is designed to remove barriers and increase partnerships between specialists, primary care providers, and genetic counselors to increase Medicare beneficiaries' access to critical services.

- As discussed, the genetic counseling IA aligns with and can also support the proposed testing-related measure: *The Mismatch Repair (MMR) or Microsatellite Instability (MSI) Biomarker Testing Status in Colorectal Carcinoma, Endometrial, Gastroesophageal, or Small Bowel Carcinoma.* This quality measure addresses a gap in the assessment of biomarker testing and can lead to identification of genetic forms of these cancer types. The genetic counseling IA supports the goals of this measure by creating an incentive for specialists to optimize identification of patients eligible for biomarker testing and efficient follow-up on test results. Additionally, the IA can promote the use of services that would identify at-risk family members through genetic testing (e.g., cascade testing) and lead to increased cancer surveillance. Studies have shown that cascade testing is a cost-effective intervention, and the effectiveness increases as more family members are identified.[25] In one study of newly-diagnosed CRC patients with Lynch Syndrome and their relatives, research found that testing twelve relatives per index patient compared to six decreased the incremental cost-effectiveness ratio from $30,331 to $12,332 per life-year saved.[26] This IA is designed to increase access to genetic counselors, which can improve overall care delivery for practices treating patients eligible for genetic testing.

Genetic Counseling IA Aligns with and Promotes Efforts Under MIPS Value Pathways (MVPs)
The genetic counseling IA aligns with several of CMS' proposed MVPs. It demonstrates the alignment of priorities between increasing access to genetic counseling services and promoting quality of care for patients living with or susceptible to oncologic and neurologic genetic conditions:

- *Advancing Cancer Care MVP:* Genetic counselors can support patients by conducting family history risk assessments, advise on the need for genetic testing and help patients make informed decisions about testing for heritable risk of cancer. Patients at risk of cancer benefit from genetic counseling by receiving guidance on appropriate risk management and surveillance frequency if they have a genetic predisposition to cancer. It is imperative for providers to understand the need,

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Lattimer, I., Arnold, M., Prior, T. W., Haut, M., … Hampel, H. (2021). Prospective Statewide Study of Universal Screening for Hereditary Colorectal Cancer: The Ohio Colorectal Cancer Prevention Initiative. JCO precision oncology, 5, PO.20.00525. https://doi.org/10.1200/PO.20.00525.

[25] Roberts MC, Dotson WD, DeVore CS, et al. Delivery of Cascade Screening for Hereditary Conditions: A Scoping Review of the Literature. *Health Affairs*. 2018;37(5). https://www.healthaffairs.org/doi/10.1377/hlthaff.2017.1630.

[26] Mvundura, M., Grosse, S. D., Hampel, H., & Palomaki, G. E. (2010). The cost-effectiveness of genetic testing strategies for Lynch syndrome among newly diagnosed patients with colorectal cancer. Genetics in medicine: official journal of the American College of Medical Genetics, 12(2), 93–104. https://doi.org/10.1097/GIM.0b013e3181cd666c

and have mechanisms in place to refer for, genetic counseling services. Increased access to genetic counselors through the interventions proposed in the genetic counseling IA, such as standardized protocols to trigger referrals for genetic services or establishment of universal testing protocols (e.g., for all patients with a recent ovarian cancer diagnosis), can also increase access to psychosocial support and identification of familial risk through cascade testing. Additionally, access to genetic counseling can supplement select quality measures and IAs, particularly where biomarker results may relate to hereditary risk.

- *Optimal Care for Kidney Health MVP:* Genetic factors are increasingly recognized as contributors to chronic kidney disease (CKD) risk, necessitating better access to genetic counseling and testing to detect risk or diagnosis earlier.[27] Given the diagnostic yield potential for sequencing-based tests, researchers recommend frequent use of genetic testing as a means for CKD diagnosis in their patients.[28] The proposed MVP focuses on providing quality treatment and managing costs associated with the disease. Access to genetic counseling services can improve quality of care delivery and affect how patients manage their kidney disease and improve their overall outcomes, and potentially reduce downstream costs associated with managing CKD or end-stage renal disease. The genetic counseling IA would improve referrals to genetic counselors for evidence-based services if family or medical history indicates a suspected genetic relationship to chronic kidney disease.

- *Optimal Care for Neurological Conditions MVP:* Genetic testing can help to not only identify the cause of neurological conditions but can also aid providers in making appropriate management decisions. Genetic counselors can support patients with epilepsy of childbearing age to make informed choices about testing and understand the implications of potential test results on pregnancy and their children's future risk of having the condition.[29] Identification of genetic etiologies to neurological conditions is also important for disease prognosis. Additionally, genetic counseling is necessary to educate patients about the implications and adaptations that may be needed to improve their quality of life. The IA would incentivize integration of genetic counselors into care teams to improve identification of appropriate diagnosis, prognosis, and treatment decisions for neurological conditions such as epilepsy, Alzheimer's Disease and Parkinson's Disease.

- *Supportive Care for Cognitive-Based Neurological Conditions MVP*: Neurologists and their patients should have access to genetic counselors who can discuss the options for genetic testing, including benefits and limitations, as well as the interpretations and implications of potential genetic test outcomes for conditions such as Alzheimer's and Parkinson's disease. Given the genetic variants associated with developing these conditions and their varying levels of risk, it is crucial for patients seeking information about genetic risk to have access to genetic counseling services that can advise on the potential outcomes and support decision-making in those who are considering genetic testing. The genetic counseling IA promotes the provision of education materials and patient-focused interventions to increase awareness and referral uptake to improve rates of completed referrals, as well as establishment of a process within a practice to improve identification of patients for genetic counseling and testing.

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[27] Devuyst O. (2014). Genetic variants and risk of chronic kidney disease. Peritoneal dialysis international: journal of the International Society for Peritoneal Dialysis, 34(2), 150. https://doi.org/10.3747/pdi.2014.00063.

[28] Knoers, N., Antignac, C., Bergmann, C., Dahan, K., Giglio, S., Heidet, L., Lipska-Ziętkiewicz, B. S., Noris, M., Remuzzi, G., Vargas-Poussou, R., & Schaefer, F. (2022). Genetic testing in the diagnosis of chronic kidney disease: recommendations for clinical practice. Nephrology, dialysis, transplantation: official publication of the European Dialysis and Transplant Association - European Renal Association, 37(2), 239–254. https://doi.org/10.1093/ndt/gfab218.

[29] Wojcik A. Genetic Testing for Epilepsy. Epilepsy Foundation. Dec. 2020. https://www.epilepsy.com/causes/genetic/testing#Why-Is-Genetic-Testing-For-Epilepsy-Important

- *Promoting Wellness MVP:* The genetic counseling IA can supplement and support the goals of the proposed breast and CRC screening measures through development of a standardized protocol to trigger referral for genetic services for appropriate clinical scenarios. For instance, if a patient's family or medical history indicated a suspected cancer risk, such as Lynch Syndrome or a *BRCA1/2* genetic variant, the implementation of a referral protocol could lead to earlier diagnosis and increased patient understanding of their risks. Furthermore, improving access to genetic counselors can support overall patient wellness by evaluating and addressing psychosocial aspects of care, including increasing patient empowerment for uptake of recommended services, patients' ability to adapt after being diagnosed with a genetic condition, and patients' adherence to care plans by providing context to their diagnoses.

NSGC appreciates the opportunity to comment on the proposed Physician Fee Schedule and looks forward to continuing to work towards advancing the interests of the patients who benefit from genetic counseling and driving quality patient care through improved access to genetic services. NSGC maintains the importance of the *Improve Access to Genetic Counseling and Testing* IA. The IA closes critical gaps in the CMS quality program related to genetic counseling and testing needed for high-quality, efficient care, and we strongly urge CMS to adopt this IA into the MIPS program. Alternatively, if CMS has identified overlap between the proposed genetic counseling IA and IAs currently in the MIPS Inventory, including IAs that broadly focus on care coordination, we would advocate for the inclusion of the genetic counseling interventions in the validation criteria. This would allow clinicians seeking to meet the activity to demonstrate completion of genetic counselor integration into multidisciplinary care teams, development of a standardized protocol to trigger genetic services referral, establishment of a universal testing protocol or process to improve identification of genetic counseling and testing needs, or provision of patient educational materials.

The following organizations and individuals have endorsed the proposed IA and support the inclusion of the IA in the MIPS IA Inventory:

- American Gastroenterological Association (AGA) Quality Committee
- Association of Community Cancer Centers (ACCC)
- Cancer Support Community (CSC)
- Family Heart Foundation
- Facing Our Risk of Cancer Empowered (FORCE)
- Jamie Tyrone, Author and Founder of Beating Alzheimer's by Embracing Science (BABES)
- Parkinson's Foundation

For questions and further information, please contact Meghan Carey, Executive Director, at mcarey@nsgc.org.

Thank you,

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