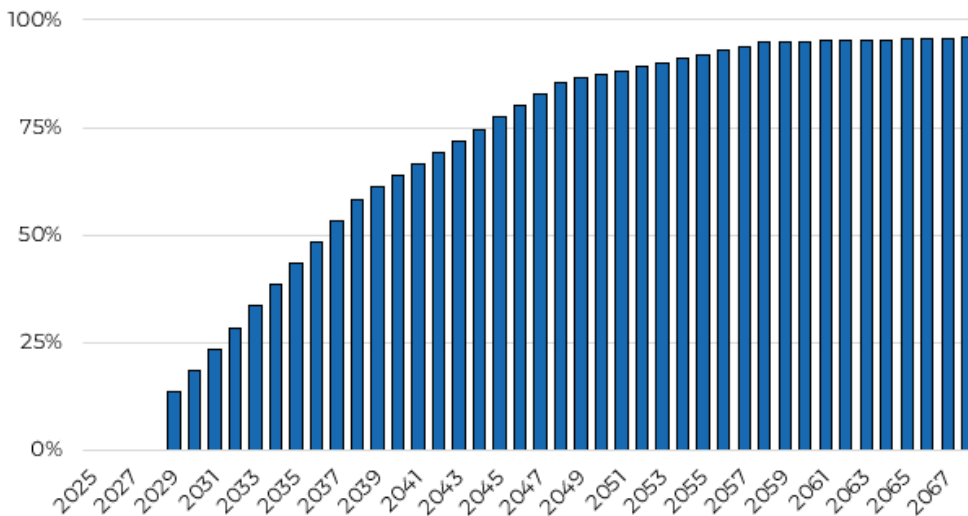


December 17, 2024

[GRAL, EXAS, GH] Multi-Cancer Test Coverage: Details Fall Flat

While positive on its face, the inclusion of multi-cancer early detection (MCED) screening test [GRAL, EXAS, GH] coverage provisions in [tonight's](#) continuing resolution (CR) to fund the government through March 14 leaves much to be desired. The measure would merely *allow* – rather than *require* – Medicare coverage of such tests starting in 2029, initially apply to just ~13% of beneficiaries (those aged 50-65) while increasing the top end by one year annually, and cap payments at ~\$500 per test until 2031, at which point rates will be based on the weighted median of commercial plan reimbursement.

Implied MCED Medicare Eligibility



Source: Medicare Monthly Enrollment, CMS Program Statistics

Coverage Timeline & Performance Standards

As [outlined](#) in the bill [p. 507], coverage of MCED screening tests cannot be made available until Jan. 1, 2029, and only those meeting as yet undetermined performance criteria will be eligible:

*“The term ‘multi-cancer early detection screening test’ means a test furnished to an individual for the concurrent detection of multiple cancer types across multiple organ sites **on or after January 1, 2029**, that – (A) is cleared under 510(k), classified under section 513(f)(2), or approved under section 515 of the Federal Food, Drug, and Cosmetic Act...[and] (C) the Secretary determines is – (i) **reasonable and necessary** for the prevention or early detection of an illness or disability”*

John Leppard

202-935-0238

john.leppard@capitolpolicypartners.com

GRAIL, LLC (GRAL)

Price: \$23.62

52-Week High: \$24.92

52-Week Low: \$12.33

EXACT Sciences Corporation (EXAS)

Price: \$60.37

52-Week High: \$79.62

52-Week Low: \$40.62

Guardant Health Inc (GH)

Price: \$34.84

52-Week High: \$38.53

52-Week Low: \$15.81

The legislation makes clear that the determination of whether a given test is “reasonable and necessary” will take place via the National Coverage Determination (NCD) process, much as had been the case under the [NCD](#) for colorectal cancer (CRC) screening using blood-based biomarker tests. Investors will recall that, in addition to mere FDA approval, CMS established preemptive test performance criteria (sensitivity \geq 74%, specificity \geq 90%) that all approved offerings must meet to be eligible for coverage.

It is unlikely that CMS would select identical thresholds to CRC for a multi-cancer product, but with GRAL’s Galleri [showing](#) an overall sensitivity of just 51.5%, as well as stakeholder [input](#) from a 4Q24 FDA panel suggesting that a broader mortality / clinical utility benefit should be identified, it remains to be seen where exactly the line for coverage will be drawn.

Capping Reimbursement

As outlined on [p. 509](#) of the text (our emphasis):

*“The payment amount for a multi-cancer early detection screening test (as defined in section 1861(nnn)) is – (A) with respect to such a test furnished **before January 1, 2031, equal to the payment amount in effect on the date of the enactment of this subsection for a multi-target stool screening DNA test.**”*

The phrase “multi-target stool screening DNA test” refers to EXAS’s Cologuard (CPT 81528), per the [NCD](#) on the subject, 4Q24 reimbursement for which is set at \$508.87. While CMS [recently](#) set a payment rate of \$592 for EXAS’s next generation Cologuard Plus (0464U), it does not take effect until Jan. 1, 2025. Therefore, the rate that would be “in effect on the date of enactment” would be \$509.

In other words, the legislation stipulates that any MCED screening test that meets CMS’s eventual coverage criteria will be paid no more than \$509 up through YE 2030, at which point rates would be adjusted to reflect the weighted median of commercial plan reimbursement.

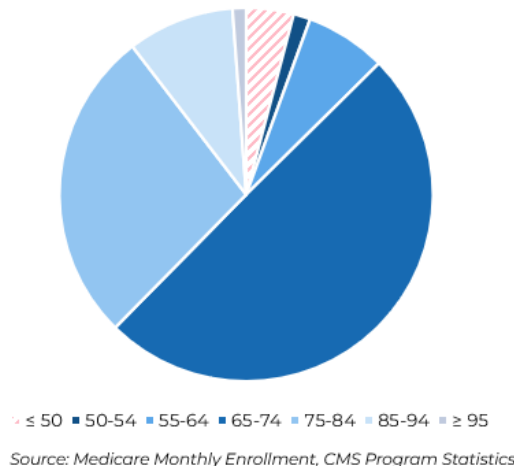
Age Limitations Leave Most Beneficiaries Ineligible

As outlined on [pgs. 509-510](#), covered tests may only be used in those aged 50 to 65 starting in 2029 – or just ~13% of total Medicare beneficiaries – with the top end of that range expanding by just one year annually (our emphasis):

*“(A) **No payment may be made** under this part for a multi-cancer early detection screening test furnished during a year to an individual if – (i) such individual – (I) is **under 50 years of age or**; (II) as of January 1 of such year, **has attained the age specified in subparagraph (B) for such year.**”*

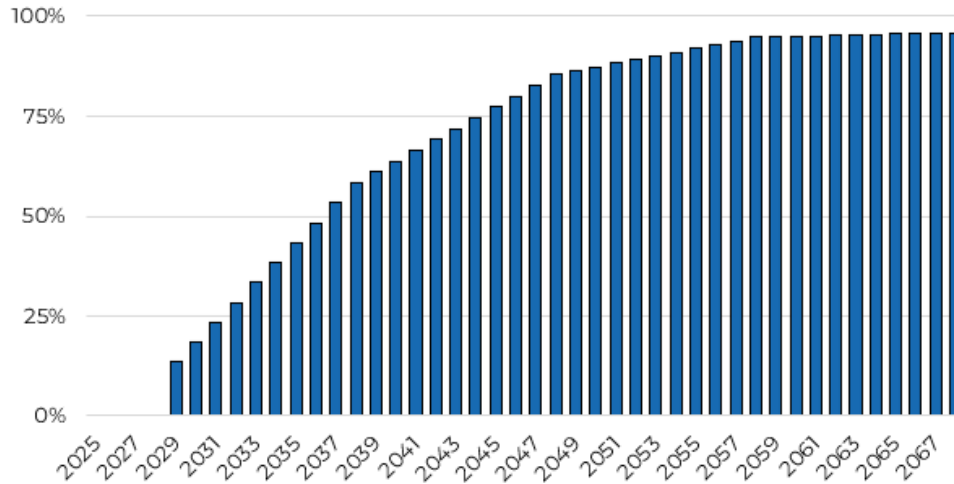
*“(B) **Age Specified** – For purposes of subparagraph (A)(i)(II), the age specified in this subparagraph is – (i) **for 2029, 65 years of age**; and (ii) for a succeeding year, the age specified in this subparagraph for the preceding year, **increased by 1 year.**”*

Medicare Population By Age



While Medicare enrollment data [\[here, here\]](#) only gives generalized age bands (e.g., 65-74), as opposed to year-by-year, a normal distribution suggests that, beginning in 2029, just ~13% of total beneficiaries would be eligible for coverage, with that figure remaining below 50% until the late 2030s.

Implied MCED Medicare Eligibility



Source: Medicare Monthly Enrollment, CMS Program Statistics

Even this may be an overestimate given that, as the population ages and life expectancy increases, we suspect the total number of beneficiaries in the age bands shown above would be more heavily weighted towards the higher end of each range rather than allocated along a normal distribution.

DISCLOSURES AND DISCLAIMERS

Analyst Certification

The analyst, Capitol Policy Partners, primarily responsible for the preparation of this research report attests to the following: (1) that the views and opinions rendered in this research report reflect his or her personal views about the subject companies or issuers; and (2) that no part of the research analyst's compensation was, is, or will be directly related to the specific recommendations or views in this research report.

Analyst Certifications and Independence of Research.

Each of the Capitol Policy Partners analysts whose names appear on the front page of this report hereby certify that all the views expressed in this Report accurately reflect our personal views about any and all of the subject securities or issuers and that no part of our compensation was, is, or will be, directly or indirectly, related to the specific recommendations or views of in this Report. Capitol Policy Partners (the "Company") is an independent equity research provider. The Company is not a member of the FINRA or the SIPC and is not a registered broker dealer or investment adviser. Capitol Policy Partners has no other regulated or unregulated business activities which conflict with its provision of independent research.

Limitation Of Research And Information.

This Report has been prepared for distribution to only qualified institutional or professional clients of Capitol Policy Partners. The contents of this Report represent the views, opinions, and analyses of its authors. The information contained herein does not constitute financial, legal, tax or any other advice. All third-party data presented herein were obtained from publicly available sources which are believed to be reliable; however, the Company makes no warranty, express or implied, concerning the accuracy or completeness of such information. In no event shall the Company be responsible or liable for the correctness of, or update to, any such material or for any damage or lost opportunities resulting from use of this data. Nothing contained in this Report or any distribution by the Company should be construed as any offer to sell, or any solicitation of an offer to buy, any security or investment. Any research or other material received should not be construed as individualized investment advice. Investment decisions should be made as part of an overall portfolio strategy and you should consult with a professional financial advisor, legal and tax advisor prior to making any investment decision. Capitol Policy Partners shall not be liable for any direct or indirect, incidental or consequential loss or damage (including loss of profits, revenue or goodwill) arising from any investment decisions based on information or research obtained from Capitol Policy Partners.

Reproduction And Distribution Strictly Prohibited.

No user of this Report may reproduce, modify, copy, distribute, sell, resell, transmit, transfer, license, assign or publish the Report itself or any information contained therein. Notwithstanding the foregoing, clients with access to working models are permitted to alter or modify the information contained therein, provided that it is solely for such client's own use. This Report is not intended to be available or distributed for any purpose that would be deemed unlawful or otherwise prohibited by any local, state, national or international laws or regulations or would otherwise subject the Company to registration or regulation of any kind within such jurisdiction.

Copyrights, Trademarks, Intellectual Property.

Capitol Policy Partners, and any logos or marks included in this Report are proprietary materials. The use of such terms and logos and marks without the express written consent of Capitol Policy Partners is strictly prohibited. The copyright in the pages or in the screens of the Report, and in the information and material therein, is proprietary material owned by Capitol Policy Partners unless otherwise indicated. The unauthorized use of any material on this Report may violate numerous statutes, regulations and laws, including, but not limited to, copyright, trademark, trade secret or patent laws.