

FAQ for Patient Access to Costly and Curative Therapies (PACCT)

PACCT is a unique risk predictability solution brought to you by OutcomeRx Insurance Management Services, LLC, and reinsured by United States Fire Insurance Company and Ironshore Indemnity Inc., both A.M. Best A Rated insurers.



PACCT provides financial risk protection for payors and other risk bearing entities while ensuring that patients receive timely access to potentially curative therapies at qualified facilities.

FREQUENTLY ASKED QUESTIONS

Q: Why Do You Need PACCT?

A: To make patient access to curative therapies possible through predictable risk coverage. Cell and gene therapies (CGTs) are among the newest pharmaceutical innovations to treat and potentially cure diseases. It is estimated that by 2025, 10 to 20 new therapies will be approved each year^{1,2}. Today, the drug cost to treat a patient with these therapies ranges from \$850,000 to \$3.5 million, and future therapies across other rare disease states are estimated to cost \$2 to \$5 million^{3,4}. PACCT is designed to maintain focus on patient health and their families' ability to support them. PACCT enhances patient access to life-changing therapies by offering financial predictability to health plans (commercial and government) and other risk bearing entities to protect their members from unexpected, and potentially catastrophic costs.

Additionally, the administration cost of some of these therapies can exceed 2x the therapy cost.

Q: How does PACCT Work?

A: Covered plans who purchase PACCT will pay a Per Member Per Month or Per Employee Per Month (PMPM/PEPM) premium to OutcomeRx for first dollar or risk sharing adjusted coverage of covered CGTs up to specified cost limits, subject to the terms of coverage. Coverage applies to individuals diagnosed after the coverage inception date and/or those that have not received an order for a covered therapy prior to the coverage inception date*.

Q: How Is the Coverage Provided by PACCT Unique?

A: We provide an independent, flexible solution that covers various payor types and broader risk takers, including carriers. Furthermore, the solution is designed to incorporate therapies as they are approved and does not mandate coverage adjustment. This approach empowers our clients to choose what coverage is valuable for their business while mitigating excess upfront expense.

Q: Where Is PACCT Coverage Available?

A: PACCT is available nationwide, subject to terms and conditions, however, it is currently offered only through reinsurance channels. Broader coverage will be available on a limited basis in the future.

Q: When Can PACCT Be Implemented?

A: The coverage is available for immediate effective dates.

Q: How Does PACCT Interact with Other Stop Loss or Reinsurance Coverage?

A: PACCT is an independent offering that covers the cost of the therapies and/or administration up to specified amounts; therefore, it is important that any in-force or future Stop Loss or Reinsurance agreements contemplate PACCT coverage. OutcomeRx consults directly with clients and other entities to ensure there is proper coverage in place that mitigates current and future premium implications. Prospective buyers should verify whether their Reinsurance and Stop Loss providers have already included PACCT in their coverage offerings.

PACCT PRODUCT COST AND RISK MANAGEMENT

Q: What Is the Cost For PACCT?

A: PACCT coverage will be a client specific, actuarially determined PMPM or PEPM rate based upon the covered population and geographic location(s). For example, a commercial health plan in one state would have a different PMPM/PEPM than in a neighboring state's Medicaid plan. Once the premium rate is calculated, the client will have a predictable monthly cost and controlled risk exposure for the covered therapies and their administration cost. Additionally, PACCT provides an option for including new therapies in the coverage as approvals occur.

Q: Do Payors Need PACCT If They Don't Currently Have a Member Who Requires a Covered Therapy?

A: PACCT is designed to help payors mitigate the financial and frequency risk exposure associated with these costly therapies. Payors might not currently have a patient requiring one of these therapies, but in the event a member is diagnosed with one of the covered diseases and requires an associated therapy, PACCT provides clients with budget predictability based on population driven rating versus a one-size-fits-all strategy.

Q: If the Plan Experiences Claims in Excess of Charged Premium, Is There Risk Exposure?

A: Due to the nature of coverage, each plan pays a PMPM/PEPM rate based on their own risk profile. If the plan pays the premium rate, they will receive coverage for covered therapies, so long as the therapies are deemed medically necessary for their plan members, subject to the terms of the in force reinsurance agreement. PACCT is reinsured by United States Fire Insurance Company and Ironshore Indemnity Inc., both A rated US Insurers (AM Best rated).

Q: What Is The Cost of The PACCT Covered Therapies?

A: The cost of specific covered therapies ranges from \$750K to \$3M for currently covered therapies. PACCT is designed to ensure that patients can quickly access these therapies while shielding them and plan providers from these potentially prohibitive costs.

Q: If the Plan Has More Patients in Need of Covered Therapies Than Expected, Are They Still Covered?

A: Yes. PACCT is designed to ensure that all plans and their members who meet the Reinsurance coverage guidelines are covered under the PACCT product.

COMPANY AND DESIGN

Q: Why OutcomeRx?

A: OutcomeRx Insurance Management Services, LLC was formed in 2020 to address the patient, manufacturer, and payor challenges in the evolving Cell and Gene Therapy (CGT) market. OutcomeRx, in conjunction with our partners, develop financial, Reinsurance, and warranty products that address the efficacy and actuarial risk associated with CGTs. We have been at the forefront of providing financial risk mitigation for emerging cell and gene-based therapies and have rapidly expanded coverage as more therapies receive FDA approval. OutcomeRx also has the unique distinction of providing both PACCT reinsurance, as well as therapy warranties that can provide even greater flexibility for access to CGTs.

WHAT'S NEXT?

Q: Will Additional Therapies Continue to Be Included in Coverage?

A: OutcomeRx anticipates adding additional covered products as new therapies that fit within our PACCT solution coverage criteria gain approval. Due to the complex FDA approval processes, we actively monitor the therapy pipeline and forecast the impact of possible approvals to all clients. Additionally, PACCT is constructed to be flexible and can quickly adjust to accommodate new therapies across disease states as they receive FDA approval. Any additional drugs included in the coverage may affect the PACCT product PMPM/PEPM charge. However, existing clients will not be required to adopt new therapy coverage.

If you have any additional questions, please reach out to Brooks Wildasin.

Brooks Wildasin, Chief Underwriting Officer
bwildasin@OutcomeRx.com | OutcomeRx.com

1 Cl Quinn, Casey, et al. "Estimating the clinical pipeline of cell and gene therapies and their potential economic impact on the US healthcare system." Value in Health 22.6 (2019): 621-626. Available at [https://www.valueinhealthjournal.com/article/S1098-3015\(19\)30188-3/fulltext](https://www.valueinhealthjournal.com/article/S1098-3015(19)30188-3/fulltext)

2 FoCUS Paying for Cures Toolkit. Expected availability to 2031. <https://www.payingforcures.org/toolkit-overview/pipeline/> Accessed April 2020.

3 Luxturna: FDA documents reveal the value of costly gene therapy. <https://www.sciencedirect.com/science/article/abs/pii/S1359644618305282>. Accessed August 2020.

4 Spinal Muscular Atrophy Therapies: ICER Grounds the Price to Value Conversation in Facts. <https://www.jmcp.org/doi/pdf/10.18553/jmcp.2019.25.issue-12#page=12>. Accessed August 2020.

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*Other conditions may apply.