Advancing Cell & Gene Therapy

The Reimbursement Process for CGTs

The following page has an overview of how Canadian governments make decisions about whether and how to fund cell and gene therapies (CGTs) through public programs. Health decision-makers need to ensure Canada has the funding and regulatory mechanisms, health system capacity, and clinical expertise to provide timely access to this new generation of therapies.

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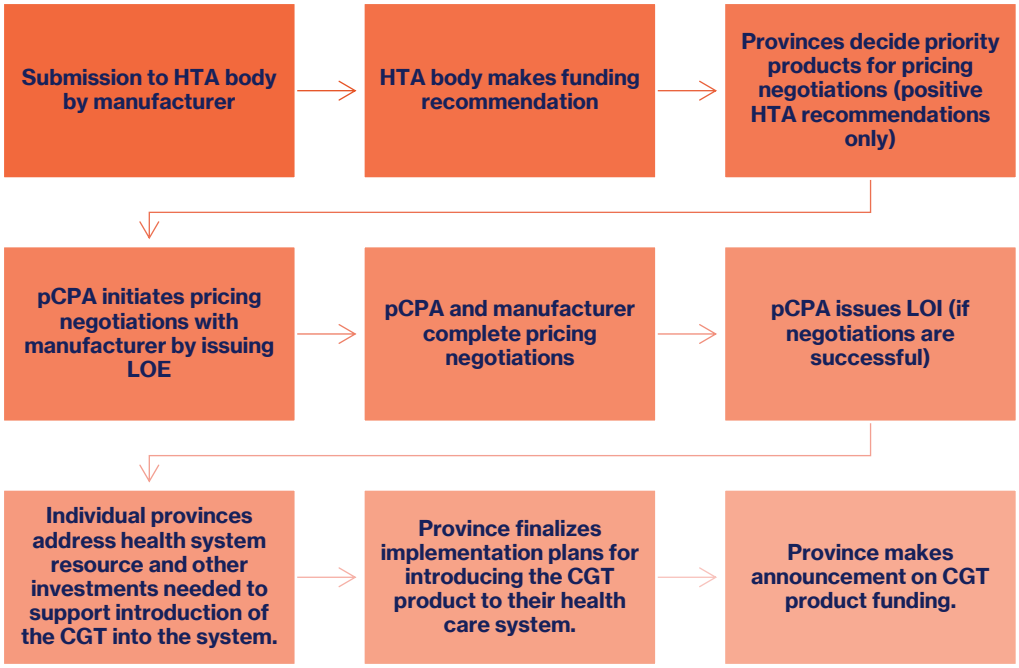
Many of the steps outlined below are similar to those taken with more traditional pharmaceutical products (e.g., HTA evaluation, pCPA pricing negotiations).[1] The overall time to patient access for CGTs is impacted by three key factors: 1) the length of the HTA process (approximately 6 months), 2) the length of the pCPA negotiation process (approximately 300 days on average [for consideration and negotiation of the file]),[2] and 3) the provincial funding process. The highly technical nature of many CGTs means that the process of achieving reimbursement at the provincial level can be lengthy due to the time and effort needed to finalize implementation plans.

For instance, for some products specific health care centres are designated as sites for administering CGTs to patients, because of the need for access to intensive care hospital beds and/or qualified health care providers who know how to manage patients receiving these products. It takes time to organize these resources, so successful integration of CGTs into the health system requires a great deal of collaboration between health care practitioners, institutions, governments, and manufacturers.



Abbreviations: CGT – cell and gene therapy; HTA – health technology assessment; LOE – Letter of Engagement; LOI – Letter of Intent; pCPA – pan-Canadian Pharmaceutical Alliance

Determining the mechanisms for provincial funding for a CGT is also more complex than that for traditional medications, as different provinces may use different sources of funding for different types of CGTs based on the resources required to administer the product (e.g., are hospital resources required?). For example, the table on the following page outlines the three different government programs within the Ontario Ministry of Health that provide funding for different types of CGTs. (**NOTE:** funding source details are not transparent in all provinces.)

[1] Pan-Canadian Pharmaceutical Alliance. pCPA Brand Process Guidelines (August 2023). https://www.pcpacanada.ca/sites/default/files/eng/pCPA_Brand_Process_Guidelines.pdf
[2] Morse Consulting. pCPA Quarterly Update (Q1 2024). https://morseconsulting.ca/morse-consulting-releases-its-pcpa-quarterly-update-q1-2024/

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Product	Indication	Funding program	Comments
Cell Therapies			
Breyanzi®, Kymriah®, Tecartus®, Yescarta®	Various blood cancers	CAR-T Therapy Funding Program*	Drug and clinical care costs (e.g., hospital-based costs) covered for patient
Gene Therapies			
Luxterna®	Retinal dystrophy	High Cost Therapy Funding Program*	Drug and clinical care costs (e.g., hospital-based costs) covered for patient
Zolgenzma®	Spinal muscular atrophy	Exceptional Access Program	Ontario Drug Benefit eligibility and payment policies apply (e.g., co-pays, deductibles, etc.), similar to other provincially funded medications

* Funded via Provincial Programs within the Ministry of Health, rather than through the provincial drug program.