

Conversion of Prograf to Sandoz Immediate Release Tacrolimus for BC Transplant Patients: Information for Clinicians

Background:

BC Transplant currently funds Prograf tacrolimus (immediate release) manufactured by Astellas Pharma Canada. In spring 2019, BC Transplant and BC Renal completed a joint Request for Proposal (RFP) for immediate release tacrolimus. Following an extensive review by a multi-disciplinary team, the award was given to Sandoz Canada for their immediate release tacrolimus product. **As a result of the new contract award, BC Transplant patients will start to receive Sandoz tacrolimus in the Fall of 2019.** This medication conversion will not impact patients receiving the long-acting formulation of tacrolimus (Advagraf).

Clinical Evidence:

Sandoz immediate release tacrolimus is a bioequivalent drug that has been approved by Health Canada and is already in widespread use in other provinces. In addition, BC Transplant and BC Renal evaluated a number of clinical studies that collectively confirm safety, efficacy and similar pharmacokinetic profiles for the majority of transplant patients who switched between Prograf and alternate brands of immediate release tacrolimus.

For renal and liver transplant recipients, one study (Alloway et al. (2017)) compared Prograf with alternate tacrolimus products (Sandoz, Dr. Reddy) using pharmacokinetic parameters to successfully demonstrate bioequivalence. Another study (Bloom et al. (2013)) on renal subpopulations (e.g. female, African American, diabetes, steroid use) also confirmed similar outcomes regardless of patient characteristics. De novo renal populations were studied in a large multicentre, randomized study (Arns et al. (2017)). The outcomes showed no relevant difference in pharmacokinetic parameters between Prograf and the alternate brand. Comparable trough levels between Prograf and the alternate brand were demonstrated in renal, liver and heart transplant recipients in a study by Spence et al. (2012). For pediatric renal transplant recipients, negligible change in pharmacokinetic parameters or allograft function were noted in a conversion study by Naicker et al. (2017). A British Columbia conversion study of glomerulonephritis patients (Barbour et al. (2018)) demonstrated no difference in mean tacrolimus levels and favourable outcomes.

System and Patient Benefits:

- Enable enhanced patient experience focused on individual safety and long-term health outcomes through a robust implementation approach and partnerships with multi-disciplinary teams.
- Allows BC Transplant the opportunity to maximize resources, expand coverage for new treatments, and improve patient access to more medications.
- Enhance PHSA and BC Transplant's expertise in implementation science of medication conversions that could be scalable or transferrable to other clinical areas.

Clinician and Patient Engagement:

As a clinician, you can expect to receive ongoing communications and clinical support tools from BC Transplant throughout the conversion period. Pharmacy partners will be notified by BC Transplant to stock Sandoz tacrolimus prior to the conversion. The transplant patients currently on Prograf tacrolimus will receive a letter and patient-focused education by their transplant care teams. BC Transplant will have patient handouts, posters and medication conversion tools available to support this project.

Important Dates to Note:

The projected medication conversion will begin in fall 2019 and is anticipated to complete by early spring 2020.

Pre-Conversion Dates	
Early Oct. 2019:	Temporary clinician funding offered for additional pharmacist and nursing staffing at the post-transplant clinics to support the medication conversion across the province.
Mid Oct. 2019:	Transplant clinicians and front-line staff will receive communication via email, as well as clinical support tools and medication conversion reporting tools available on the BC Transplant website.
	Transplant pharmacy partners will implement updates to pharmacy information systems.
End Oct. 2019:	Patients will receive medication conversion communication from BC Transplant.
	Transplant pharmacy partners to have Sandoz tacrolimus ordered and stocked to enable site readiness.
Nov. to Dec. 2019:	Patient-focused education sessions and patient support materials will be provided by BC Transplant to patients and clinics.
Conversion Go-Live Dates	
Nov. 4, 2019:	Initiation of de novo (new) transplant patients on Sandoz tacrolimus will commence at BC Children’s Hospital and Vancouver General Hospital .
Nov. 18, 2019	Conversion of current transplant patients from Prograf to Sandoz tacrolimus will commence at Interior Health Authority post transplant clinics: Kamloops, Kelowna, Penticton, Trail ; and in the Northern Health Authority: Prince George .
Jan. 6, 2020 – Mar. 31, 2020	<p>Initiation of de novo (new) transplant patients on Sandoz tacrolimus will commence at St. Paul’s Hospital.</p> <p>Conversion of current transplant patients will commence at all remaining clinics at Vancouver General Hospital, BC Children’s Hospital, St. Paul’s Hospital, Surrey, Victoria and Nanaimo.</p> <p>Note: Patients will be expected to use up their existing supply of Prograf before transitioning to Sandoz tacrolimus. It is anticipated that the immediate-release tacrolimus medication conversion be completed on or before Mar. 31, 2020.</p>

Contact Information:

For more information on conversion processes and workflows, clinical support tools, references and frequently asked questions (FAQ), please visit www.transplant.bc.ca/tacrolimusswitchHP.

If you have further questions, please contact BC Transplant by emailing pharmacy@bct.phsa.ca.