

Navigating the TIL Landscape: Creating and Implementing Policies for New Immune Effector Cell Therapy Products

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Problem

- Tumor infiltrating lymphocytes (TIL) therapy, a type of immune effector cell therapy, was FDA approved February 16, 2024 for metastatic melanoma
- A new product required that cell therapy nurse coordinators develop navigation plans, insurance approval process, and coordinate with multiple teams to streamline patient care
- Cell therapy nurse coordinators were involved with developing new policies and procedures, creating patient-specific education materials, and consent forms

Goal

- Successfully onboard a new cell therapy product through
 - Development of new policies and procedures
 - Creation of patient-specific educational materials and consent forms
 - Identifying and communicating with key stakeholders for review of initial policies
 - Ensuring continuous quality improvement occurs related to policies and procedures for new therapy

Strategy

- Key stakeholders were gathered for discussions centered around policies and procedures and the review
- Policies were created, discussed and reviewed relating to treatment roadmaps, patient education, patient evaluation, patient selection, Transplant Optimization Program criteria, scheduling surgical resection, post TIL vaccinations, post TIL testing, ideal timing for admissions such as days of the week to best accommodate staffing and number of patients who can be infused in a week, and interleukin-2 (IL-2) timing for administration and checklists

Table 1. Key Stakeholders

Cell Therapy Nurse Coordinators	Melanoma Physician (working with cell therapy)	Surgical Team
Clinical Director of Cell Therapy	Quality and Regulatory Specialist	Cell Therapy Pharmacist
Oncology Clinical Nurse Specialist	Oncology Nurse Educators	Inpatient Nurse Management
Inpatient Cell Therapy Advanced Practice Providers	Outpatient Cell Therapy Advanced Practice Providers	Cell Processing Lab Staff

Table 2. Policies Created

TIL Therapy Protocol Checklist	Follow Up and Evaluation of Patients Undergoing TIL Therapy (Post Infusion)
TIL Therapy Patient Selection Criteria	TIL Therapy Recipient Evaluation and Workup
Infusion of Cryopreserved TIL Therapy	IL-2 Infusion Checklist and Toxicity Management

Impact

Cell therapy nurse coordinators collaborated with a group of key stakeholders (Table 1) to develop policies (Table 2) and patient specific education materials and consents (Figure 1). A continuous quality improvement plan was developed, as seen in Figure 2. Today 49 patients have been collected at least once and 32 patients have successfully received their cells

Figure 1. Patient Specific Education and Consents

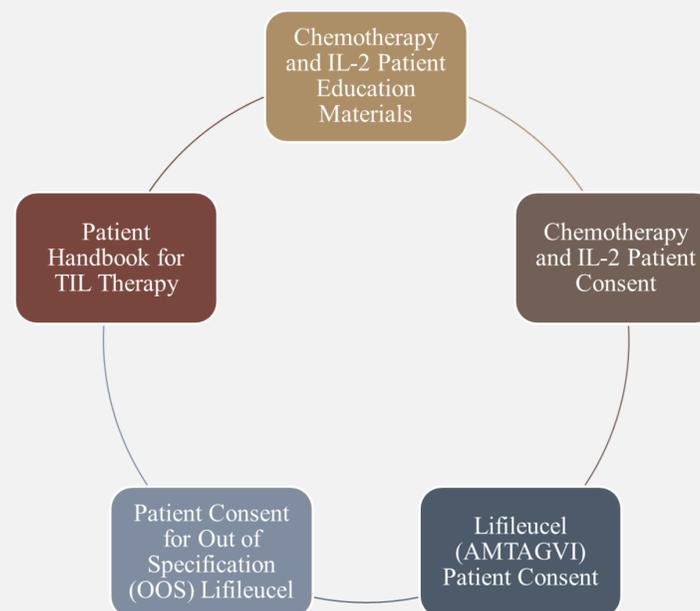


Figure 2. Timeline of Policy Development Using Continuous Improvement



Conclusions

- Identifying key stakeholders early in the process is crucial to success
- Discuss plan with key stakeholders to implement a comprehensive approach to successfully onboard a new product in a timely and safe fashion
- These plans need to include what policies are needed, which educational materials need to be created, and a plan to implement continuous quality improvement for policies
- A reevaluation plan during initial roll out is important to maintain patient safety, and all stakeholders must be aware of these plans and actively participate
- As sites onboard new cell therapy products, considerations for how to handle out of specification products must be addressed. Ideally, an out of specification protocol could be on boarded concurrently as the new product.

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