Penn Medicine

The Impact of Health System Specialty Pharmacy in Oncology Patients

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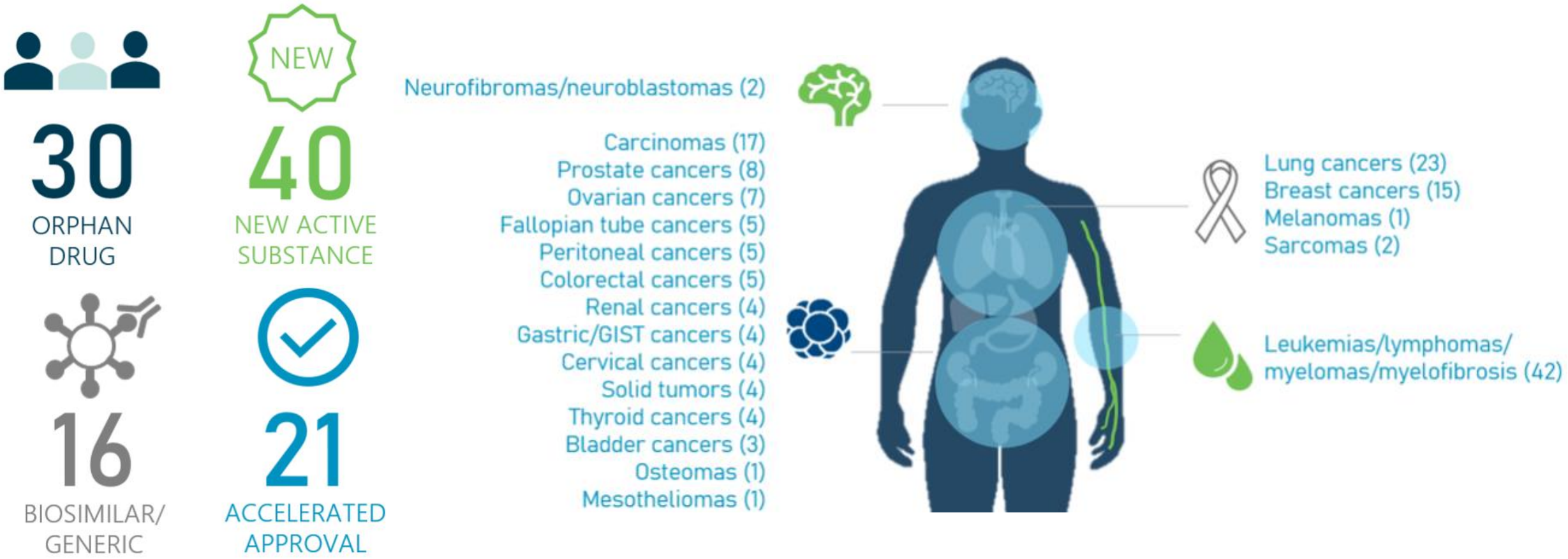
This presentation includes discussion of off-label usage of medications

Cancer Targeted by Medicines Approved/Recommended in 2020



CATO SMS. EMA & FDA Approvals and recommendations in 2020 for oncology drugs and diagnostics/devices. Jan. 18, 2021. Accessed Sep. 5, 2021. Websites - AMA Citation Style - Research Guides at George Washington University (gwu.edu)

A High-Risk Population

- Over 25 million oral doses administered annually
- Error rate: 8.1 errors per 100 clinic visits
- A 2006 survey of US cancer centers found:
  - 1 in 4 centers have standard safeguards
  - 1 in 5 have measures to monitor safe administration and monitoring

- American Society of Health-System Pharmacists (ASHP) Guidelines on Preventing Medication Errors with Chemotherapy and Biotherapy
  - **Administration (56%)** and **ordering (36%)** were the most common phases where errors occur
  - The exact rate of errors with oral chemotherapy is not well studied
  - The routine use of safety systems is not used for oral chemotherapy

Weingart SN, et al. BMJ. 2007;334:407-409
Gandhi TK et al. Cancer. 2005;104:2477-2483
Walsh KE, et al. J Clin Oncol. 2009;27:891-896
Weingart SN, et al. Cancer. 2010;116:10:2455-2464
Goldspiel B, et al. ASHP Council on Pharmacy Practice. 2014: 231-256

Goals of a Specialty Service

- ***Facilitate methods of increased communication between patients and pharmacists***
  - *Enhance adherence to medications*
  - *Identify potential safety issues*
  - *Allow for timely administration in accordance with prescriber directives*
  - *Health care professionals have comprehensive oncology pharmacy training or specialty certified*
  - *Employ technicians or support staff who institute standardized pathways to triage situations appropriately and escalate patient care concerns*

Schwartz RN, et al. Journal of the National Comprehensive Cancer Network. 2010;8(4): S1-S12

The Penn Pharmacy Team

Clinic
- Patients are diagnosed and evaluated
- Care plans are made
- Orders placed for treatment
- Supportive care issues managed

Clinical Specialist Pharmacy Team

Infusion Suite
- Patients receive chemotherapy teaching
- Patients receive treatment and supportive care
- Patients evaluated and triaged in the Oncology Evaluation Center

Infusion Suite Pharmacy Team

Retail and Specialty Pharmacy
- Benefits investigations are performed
- Prior authorizations are completed by a central pharmacy based team
- Grant and financial support for high cost drugs
- Delivery and refill coordination of medications
- Education and clinical support to patients and providers

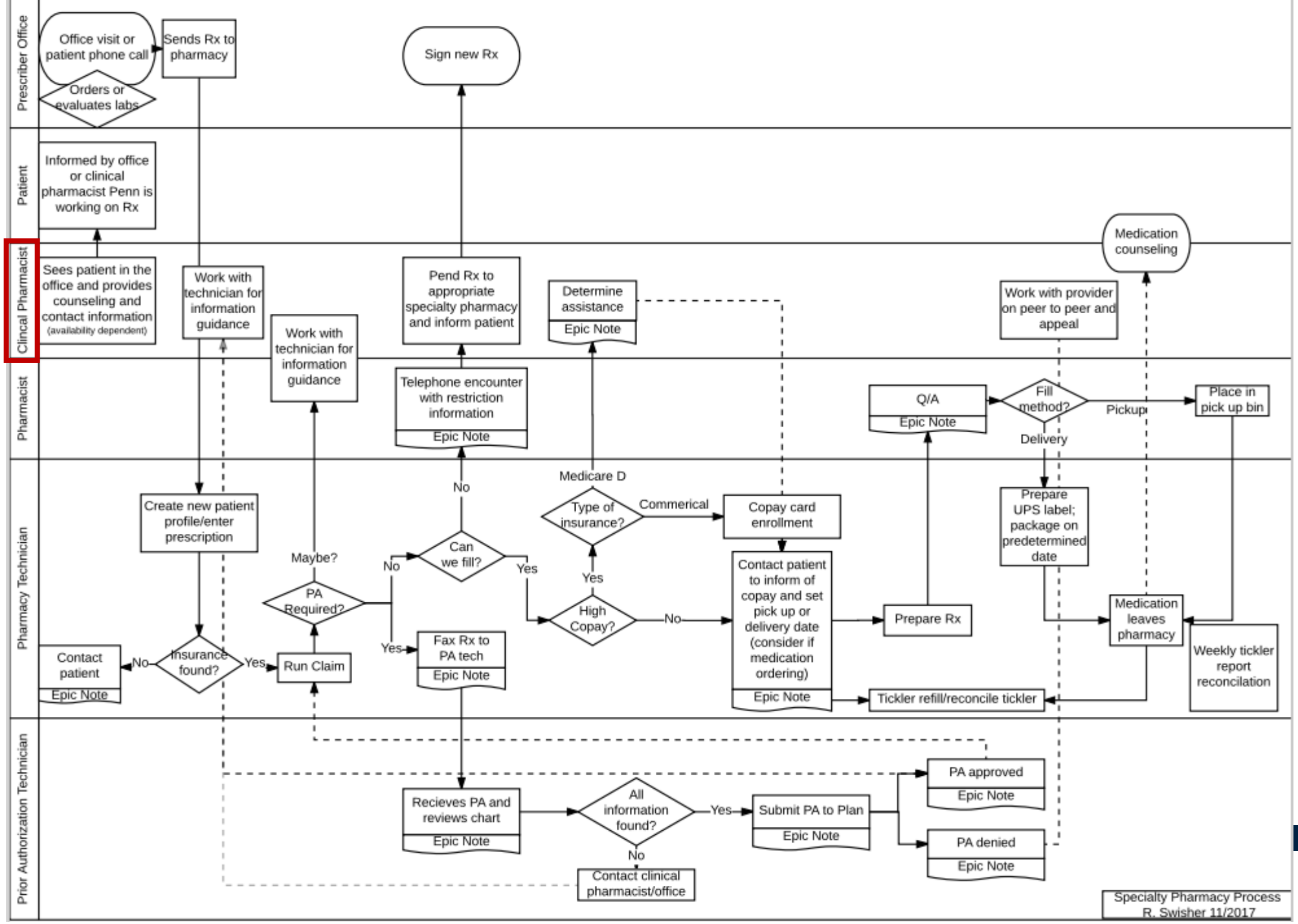
Retail and Specialty Pharmacy Team

Pharmacists	Technicians
-Front store	-Front Store
-Specialty	-Specialty Entry
-Unit Based	-Prior Authorization (PA)
-Clinical Specialist	-Pharmacy Service Representatives (PSR)
	-Billing

Image designed by: Christine G. Cambareri, PharmD, BCPS, BCOP, CSP

Penn Specialty Pharmacy Quality Metrics

- ***Fiscal Year 2021***
  - *Prior authorization approval rate:* ***83.9%***
  - *Average time to prior authorization approval:* ***1.51 days***
  - *Average time from order to delivery to patient:* ***4.4 days***
  - *Pharmacist administered immunizations:* ***2,022***
  - *Medication adherence (Medication Possession Ratio):* ***96%***
  - *Financial assistance applied for patient's out-of-pocket costs:* ***~$625,000/month***


Prescriber Office
Patient
Clinical Pharmacist
Pharmacist
Pharmacy Technician
Prior Authorization Technician
Office visit or patient phone call
Orders or evaluates labs
Sends Rx to pharmacy
Sign new Rx
Informed by office or clinical pharmacist Penn is working on Rx
Sees patient in the office and provides counseling and contact information (availability dependent)
Work with technician for information guidance
Work with technician for information guidance
Pend Rx to appropriate specialty pharmacy and inform patient
Determine assistance
Epic Note
Medication counseling
Work with provider on peer to peer and appeal
Telephone encounter with restriction information
Epic Note
Q/A
Epic Note
Fill method?
Pickup
Place in pick up bin
Delivery
Create new patient profile/enter prescription
Medicare D
Type of insurance?
Commerical
Copay card enrollment
No
Can we fill?
Yes
Maybe?
No
PA Required?
Yes
Yes
High Copay?
No
Contact patient to inform of copay and set pick up or delivery date (consider if medication ordering)
Epic Note
Prepare Rx
Prepare UPS label; package on predetermined date
Medication leaves pharmacy
Weekly tickler report reconcilation
Contact patient
Epic Note
No
Insurance found?
Yes
Run Claim
Fax Rx to PA tech
Epic Note
Tickler refill/reconcile tickler
Recieves PA and reviews chart
Epic Note
All information found?
Yes
No
Submit PA to Plan
Epic Note
PA approved
Epic Note
PA denied
Epic Note
Contact clinical pharmacist/office
Specialty Pharmacy Process
R. Swisher 11/2017

Penn Oncology Service Lines: Examples

- ***Lymphoma Program***
  - *8 Physicians*
  - *4 Advanced Practice Providers*
  - *3 Triage Nurses*
  - *Lymphoma Clinical Research Unit*
    - *2 Advanced Practice Providers*
    - *7 Nurses*
    - *6 Coordinators*
    - *2 Research Assistants*
  - *1 Clinical Pharmacy Specialist*

- ***NeuroOncology Program***
  - *3 Physicians*
  - *2 Advanced Practice Providers*
  - *3 Triage Nurses (shared)*
  - *1 Clinical Pharmacy Specialist (shared)*

- ***Sarcoma Program***
  - *1 Physicians*
  - *3 Triage Nurses (shared)*
  - *1 Clinical Pharmacy Specialist (shared)*

Pharmacist Responsibilities in the Interdisciplinary team

- ***Designing regimens***
- ***New therapy education***
  - *Robust utilization of telemedicine capabilities; especially helpful for those with cognitive dysfunction*
- ***Ensures timely delivery of all specialty medications***
- ***Manages all chemotherapy refills and laboratory monitoring***
- ***Infusion Center Responsibilities and Home Infusion Collaborations***
- ***Curation of Beacon Templates***
- ***Patient Access, Specialty Pharmacy Liaison and Financial Assistance***
- ***National Comprehensive Cancer Network (NCCN) Annual Review of Guidelines***

Academic Collaborations- Publications

Oral Oncolytics/Specialty

- **Hughes ME**, Landsburg DJ, Rubin DJ, Schuster SJ, Svoboda J, Gerson JN, Namoglu E, Nasta SD. Treatment of relapsed/refractory non Hodgkin lymphoma patients with venetoclax therapy: A single-center evaluation of off-label use. Clinical Lymphoma, Myeloma and Leukemia. 2019;19(12):791-8.
- Landsburg DJ, **Hughes ME**, Koike A, Bond D, Maddocks K, Guo L, Winter AM, Hill B, Ondrejka SL, His ED, Nasta SD, Svoboda J, Schuster SJ, Bogusz A. Outcomes of patients with relapsed/refractory double expressor B cell lymphoma treated with ibrutinib monotherapy. Blood Adv. 2019;3:132-135.

Intravenous Therapies

- Landsburg DJ, Nasta SD, Gerson JN, Svoboda J, Chong EA, Schuster SJ, Barta SK, Robinson KW, **Hughes ME**. Time-to-response for patients with relapsed/refractory diffuse large B cell and high grade B cell lymphoma treated with polatuzumab-based therapy. Leukemia & Lymphoma. 2021; DOI: 10.1080/10428194.2021.1971224.

Content/Expert Opinion

- Namoglu EC, **Hughes ME**, Nasta SD. Targeted immunotherapies to consider for B cell non-Hodgkin lymphoma. Expert Review of Precision Medicine and Drug Development. 2021; DOI: 10.1080/23808993.2021.1967142
- Tsai DE and **Hughes ME**. Prognostic factors of PTLD after SOT. In: Dharnidharka V, Green M, eds. Post-transplant lymphoproliferative disorders. Springer International Publishing. 2021. ISBN 978-3-030-65403-0
- Namoglu EC, **Hughes ME**, Plastaras JP, Landsburg DJ, Maity A, Nasta SD. Management and outcomes of sinus histiocytosis with massive lymphoadenopathy (Rosai Dorfman disease). Leukemia & Lymphoma. 2020;61(4):905-911.

Imaging/Diagnostics

- Ruff A, Ballard HJ, Pantel AR, Namoglu EC, **Hughes ME**, Nasta SD, Chong EA, Bagg A, Ruella M, Farwell MD, Svoboda J, Sellmyer MA. ^{18}F-Fluorodeoxyglucose Positron Emission Tomography/Computed Tomography Following Chimeric Antigen Receptor T-cell Therapy in Large B-cell Lymphoma. Mol Imaging Biol. 2021 Jul. Epub ahead of print. PMID: 34231105.

Patient Case: SE

- ***SE is a 62-year-old woman with T-cell lymphoma (AITL vs. nodal peripheral T-cell lymphoma)***
  - *S/P CHOEP and consolidative BEAM autologous stem cell transplant (relapsed after 10 months)*
  - *Tfh (T-follicular helper) cell phenotype*
- ***Patient visit in clinic 06/25. Clinical team (MD, NP, Pharm.D.) discussed potential for starting IV romidepsin and oral azacitidine as bridge to allogeneic stem cell transplant***
  - *Prescription sent 06/30; PA submitted and denied on 06/30*
  - *Clinical pharmacy specialist submitted urgent clinical appeal 07/01*
    - *Falchi L et al. Combined oral 5-azacytidine and romidepsin are highly effective in patients with PTCL: a multicenter phase 2 study. Blood 2021 Apr 22;137(16):2161-2170*
  - *Appeal denial 07/02; urgent external review submitted by clinical pharmacy specialist 07/06*
  - *External review approval confirmed 07/12; clinical pharmacist education completed 07/12*

Patient Case: SE

Assessment and Plan:

- Discussed indication, administration, and adverse effects of Onureg over the phone with Mrs. E[redacted] and her husband
- Received Onureg approval 07/09/2021 in the evening and able to confirm claim was valid on 07/12/2021 in the morning.
- We will set up delivery for her to receive in the mail either 07/14/2021 or 07/15/2021
- Her romidepsin infusion is scheduled on 07/16/2021; Dr. [redacted] to connect with her local oncologist to set up timing with initiating Onureg with romidepsin.
- Suggested with Cycle 1 and Cycle 2 to take prophylactic antiemetic on days of Onureg to minimize any N/V. If tolerated, can stop antiemetic prophylaxis
- Reviewed treatment schedule for Onureg is not continuous and only 14 days of ~35 day cycles.

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- ***Oral azacitidine filled by Penn Specialty Pharmacy and delivered 07/14.***
  - *From fill to door: 15 days including 2 levels of patient appeal*
- ***Regimen initiation 07/16***
  - *08/23 transplant consult initiated*
  - *Continues a clinical response to therapy*
  - *Imaging planned for early October to confirm a complete response and transition to haploidentical stem cell transplant*

Areas for Advocacy

- ***Collaborative Practice Agreements***
- ***Ambulatory Scheduling for Pharmacist Visits***
- ***Identifying Patient Acuity Scoring to Triage the Ambulatory Pharmacist's Schedule***
- ***Leveraging Decentralized Specialty Pharmacy Support to Bolster Patient Advocacy***

Acknowledgments

- ***The presenters sincerely thank:***
  - *Our patients and their families*
  - *Our interdisciplinary oncology service line teams including the Penn Lymphoma, Cellular Therapy, and the CNS Malignancy Programs*
  - *The Penn Medicine Specialty Pharmacy*

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