

# Immuno-Oncology in the Community Setting: Coordination of Care

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# Conflicts of Interest

# Objectives

Brief overview of care coordination and considerations for I-O patients in the community setting.

- FDA approved I-O agents.
- Role of Immunotherapy coordinator
- Patient selection
- Access to I-O agents
- Financial concerns/reimbursement
- Staff and patient teaching
- Adverse event monitoring.

# FDA Approved Immunotherapy for Cancer Treatment

- Non-specific immunotherapy
  - BCG
- Cytokines
  - Interferon
  - High dose Interleukin-2
- Monoclonal antibody therapy
  - Naked mAbs (alemtuzumab, trastuzumab)
  - Conjugated mAbs (ibritumomab, brentuximab, ado-trastuzumab)
  - Bispecific mAbs (blinatumomab)
  - Immuno-modulatory or checkpoint inhibitors (ipilimumab, nivolumab, pembrolizumab)
- Cancer vaccines
  - Sipuleucel-T
  - Talimogene Laherparepvec

<http://www.cancer.org/treatment/treatmentsandsideeffects/treatmenttypes/immunotherapy/immunotherapy-monoclonal-antibodies>

# Immunotherapy Coordinator

- Primary contact for patients.
- Organize and pre-screen patients for I-O regimens.
- Connect patients with Financial Advocate for early billing explanation/intervention.
- Coordinate patient care including follow up, tests/procedures, consultations.
- Educate staff and patients on potential adverse events and irAE's for timely intervention.

Dutcher, Janice, Douglas Schwartzentruer, Howard Kaufman, Sanjiv Argarwala, Ahmed Tarhini, James Lowder, and Michael Atkins. "High Dose Interleukin (Aldesleukin)-expert Consensus on Best Management Practices-2014." *Journal for Immunotherapy of Cancer* 26 Feb. 2014: 1-23.

# Immuno-Oncology Patients: Patient Selection

- Patient interview and review of medical record for pre-existing conditions, or prior adverse events.
- Communicate screening concerns to treating physician.
- Use caution when patients present with pre-existing conditions and/or prior adverse events.

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Weber, J., Yang, J., Atkins, M., & Disis, M. (2015). Toxicity of Immunotherapy for the Practitioner. *Journal of Clinical Oncology*, (33), 1-8.  
doi:10.1200/JCO.2014.60.0379

# Patient Selection cont.

- Non Specific Immunotherapy-BCG
  - Immunosuppressed patients.
  - Post-pone treatment:
    - Concurrent febrile illness, UTI, gross hematuria.
    - Do not initiate treatment for 7-14 days following biopsy, TUR, or traumatic catheterization.
  - Contraindicated for patients with active TB.
    - Active TB should be ruled out in PPD positive patients before starting treatment.

<http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM163039.pdf>

# Patient Selection cont.

- Cytokine Therapy

- Interferon

- Screen for history of significant depression or psychiatric disorder.
    - Screen for autoimmune disorders.
    - Autoimmune hepatitis
    - Decompensated liver disease

- IL-2

- Normal cardiac, pulmonary, hepatic, and CNS function at the start of therapy.
    - No evidence of CNS metastasis or treated and stable CNS metastasis without steroids.
    - Treatment associated with exacerbation of pre-existing or initial presentation of autoimmune disease and inflammatory disorders.

[https://www.merck.com/product/usa/pi\\_circulars/i/intron\\_a/intron\\_a\\_pi.pdf](https://www.merck.com/product/usa/pi_circulars/i/intron_a/intron_a_pi.pdf)

<http://www.uptodate.com/contents/adjuvant-immunotherapy-for-melanoma#H2754866>

[http://www.accessdata.fda.gov/drugsatfda\\_docs/label/2012/103293s5130lbl.pdf](http://www.accessdata.fda.gov/drugsatfda_docs/label/2012/103293s5130lbl.pdf)



# Patient Selection cont.

- Monoclonal Antibodies
  - Check package insert per mAbs for any contraindications that may be listed.

# Patient Selection cont.

- Cancer Vaccines
  - Sipuleucel-T
    - Use caution with patients that have risk factors for thromboembolic events.
  - Talimogene Laherparepvec
    - Immunocompromised patients
    - Pregnant patients

<http://www.dendreon.com/prescribing-information.pdf>  
[http://pi.amgen.com/united\\_states/imlygic/imlygic\\_pi.pdf](http://pi.amgen.com/united_states/imlygic/imlygic_pi.pdf)

# Patient Selection cont.

- **Pregnancy**
  - Check package inserts for pregnancy information.
- **Lactation**
  - Unknown whether many of these agents are transmitted through breast milk.
- **Contraception**
  - Advise use of contraception during treatment and after treatment per package insert recommendations.
- **Fertility**
  - Fertility studies have not been done in many of the newer agents such as PD-1. So this may be something to discuss with younger patients.

# Access to Immuno-Oncology Agents

Several barriers to accessing I-O agents:

- Low patient volumes.
- P&T committee approval.
- I-O agent cost.

# Coordinating Financial Concerns

- Third party payers
  - Pre-determination
- Medicare/Medicaid
  - No pre-determination
- Financial Counseling
  - Address concerns early to avoid unnecessary worry for the patient.
  - Discuss out of pocket costs.
  - Utilize assistance programs

Ubel, P., Abernethy, A., & Zafar, Y. (2013). Full Disclosure-Out-of-Pocket Costs as Side Effects. *New England Journal of Medicine*, 369(16), 1484-1486.

# Assistance Programs

- A few of the assistance programs will not allow a patient to enroll prior to insurance denial.
  - Make sure the patient meets the financial qualifications for the assistance program.
  - Have all of the paperwork/financial information in place prior to treatment.
  - Submit to assistance program if insurance denial.

# Patient Education on Adverse Events

- Ongoing patient and caregiver teaching.
- Wallet cards and/or symptom logs.
- Encourage accurate reporting of adverse events.

Fecher, Leslie, Sanjiv Agarwala, Stephen Hodi, and Jeffrey Weber. "Ipilimumab and Its Toxicities: A Multidisciplinary Approach." *The Oncologist* 18 (2013): 733-43. Print.

# Staff Education on Adverse Events

- Education should include:
  - Office Staff-Triage.
  - RN Education.
  - Advanced Practice Nurses or Physician Assistants.
- Adverse event treatment algorithms.
- Late appearing side effects

Fecher, Leslie, Sanjiv Agarwala, Stephen Hodi, and Jeffrey Weber. "Ipilimumab and Its Toxicities: A Multidisciplinary Approach." *The Oncologist* 18 (2013): 733-43. Print.

Kannan, R., Madden, K., & Andrews, S. (2014). Primer on Immuno-Oncology and Immune Response. *Clinical Journal of Oncology Nursing*, 18(3), 311-326.

Ledezma, Blanca, and Annie Heng. "Real-world Impact of Education: Treating Patients with Ipilimumab in a Community Practice Setting." *Cancer Management and Research* 6 (2014): 5-14. Print.



# Adverse Event Management

- PD-1
  - Rash
    - Topical steroids and/or antihistamines.
    - Oral steroids with slow taper.
    - Consider dermatology consult.
  - Diarrhea
    - Oral anti-diarrheals.
    - Oral steroids or IV steroids with slow taper.
    - Consider GI consult with biopsy.

# Adverse Event Management

- High-dose adjuvant ipilimumab (10 mg/kg)
  - 2 cases of skin rash, diarrhea, and hypophysitis.
  - Onset for both was rash, diarrhea, hypophysitis.
  - One patient had enlarged pituitary on MRI.
  - One patient had biopsy confirmed autoimmune colitis.

# Care Coordination Between Treatment

Important to stress communication between treatments or after treatment.

- Regular follow-up phone calls by clinic staff to assess for irAE's.
- If irAE's are being experienced daily phone calls to track severity of symptoms.
- Monitor response to medications.
- Increase frequency of laboratory monitoring and/or office visits to assess irAE's.
- Instruct patient to visit emergency department if adverse event is high-grade/life threatening.

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# Care Coordination for Travel

## Proactive management prior to patient's travel plans:

- Patients should bring education/side-effect materials with them.
- Confirm patient has contact information for treating physician.
- Write prescriptions in advance.
- Encourage patient to research nearby hospitals and emergency departments.
- Instruct patient to go to emergency department if adverse events are not controlled.

Ledezma, Blanca, and Heng, Annie. "Real-world Impact of Education: Treating Patients with Ipilimumab in a Community Practice Setting." *Cancer Management and Research* 6 (2014): 5-14. Print.

# Care Coordination After Treatment

- Encourage patient to keep long-term follow-up appointments.
- Assess for new irAE's at long-term follow-up visits.
- Continue assessment and management of chronic irAE's
- Consider survivorship issues associated with long-term irAE's

Johnson, D., Friedman, D., Berry, E., Decker, I., Ye, F., Zhao, S., . . . Lovly, C. (2015). Survivorship in Immune Therapy: Assessing Chronic Immune Toxicities, Health Outcomes, and Functional Status among Long-term Ipilimumab Survivors at a Single Referral Center. *Cancer Immunology Research*, 3(5), 464-469.

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# Questions?



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# References

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