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-modulary or checkpoint inhibitors (ipilimumab, nivolumab, pembrolizumab)
- Cancer vaccines
  - Sipuleucel-T
  - Talimogene Laherparepvec

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.

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.


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 catherization.
  - Contraindicated for patients with active TB.
    - Active TB should be ruled out in PPD positive patients before starting treatment.

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

• 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.

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

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.


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.

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.


Questions?
Save-the-Date
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References


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