Positive Quality Intervention: Trifluridine / Tipiracil for Treatment of Gastric Cancer

Description:
This PQI will review patient identification and clinical considerations for this treatment option for gastric cancer.

Background:
Trifluridine/Tipiracil (Lonsurf) is approved for use in patients with gastric or gastroesophageal junction (GEJ) cancer who have failed at least two prior lines of chemotherapy (including a fluoropyrimidine, a platinum, either a taxane or irinotecan, and if appropriate, HER2/neu-targeted therapy) following results from the TAGS trial, a Phase III, multinational, randomized, double-blind trial that compared trifluridine/tipiracil plus best supportive care vs. placebo plus best supportive care. Median overall survival was 5.7 months (95% CI 4.8–6.2) in the trifluridine/tipiracil group and 3.6 months (3.1–4.1) in the placebo group.

Sequencing of treatment in advanced gastric cancer is still not well defined, but trifluridine/tipiracil serves as a viable option for 3rd and subsequent lines of treatment. It is currently the only oral option available. Clinical guidelines recommend utilizing this agent in patients who have low-volume gastric cancer with minimal or no symptoms, and are able to swallow.

PQI Process:
- Identify patients with gastric or gastroesophageal junction (GEJ) cancer who have failed at least two prior lines of chemotherapy (including a fluoropyrimidine, a platinum, either a taxane or irinotecan, and if appropriate, HER2/neu-targeted therapy)
- Consider conversation with care team with trifluridine/tipiracil as potential oral oncolytic option
- Upon receiving a prescription for Trifluridine/Tipiracil:
  - Verify appropriateness of treatment (indication, prior lines of treatment)
  - Verify correct dose: rounded to nearest 5mg (*See dosing in Supplemental Information*)
  - Check complete blood counts prior to Day 1 and on Day 15 of each cycle
    - Do not initiate cycle until ANC ≥ 1,500/mm3 and platelets ≥ 75,000/mm3
    - Hold treatment if ANC < 500/mm3, febrile neutropenia, or platelets < 50,000 mm3
  - Check liver function
    - Do not initiate therapy in patients with moderate to severe hepatic impairment (Bilirubin >1.5 ULN and any AST elevation)
Patient Centered Activities:

- Provide Oncology Chemotherapy Education (OCE) Sheet and counsel on potential side effects
- Counsel patient on dosing schedule, and administration (*see Supplemental Information)
  - Consider starting on a Monday to complete days 1-5 from Monday to Friday, break on the weekend (days 6-7), and resume Monday to Friday for days 8-12. Patient does not take therapy for days 13-28
  - Notify the patient that dose delays may be beneficial when managing adverse effects, and should not interfere with their ability to receive treatment or achieve benefit
- Provide medication and clinic appointments calendar; dosage calculator and calendar creator available at www.lonsurfhcp.com/dosing/dosage-calculator
- The most common grade 3 or worse adverse effect is neutropenia (38%)
  - In the TAGS trial, the majority of episodes were managed by delaying the next dose
  - 16% of subjects in that trial were managed with granulocyte colony-stimulating factor
- Consider antiemetic and antidiarrheal medications to manage potential patient adverse effects
- Counsel patient on safe storage, handling, and disposal of cytotoxic drugs (instruct caregiver to wear gloves)
- Provide support kit
  - Lonsurf Starter Kits contain patient and caregiver brochures, pillboxes, and thermometer

References:


Supplemental Information:

Dosing and Administration:

- 35 mg/m² (based on trifluridine) twice daily on days 1 to 5 and 8 to 12 of a 28-day cycle
- Round to the nearest 5 mg (available in 15 mg and 20 mg tablets); refer to dosing calculator available
- Maximum dose 80 mg/dose (160 mg/day)
- Administer with food and swallow tablets whole, within 1 hour after completion of morning and evening meals
- After recovery, reduce dose by 5mg/m²/dose if:
  - Patient had febrile neutropenia, uncomplicated Grade 4 neutropenia or thrombocytopenia that resulted in > 1 week delay in start of next cycle.
  - Nonhematologic grade 3 or 4 adverse reaction, except for grade 3 or 4 nausea/vomiting controlled by antiemetics or grade 3 diarrhea responsive to antidiarrheal medication.
  - Maximum of 3 dose reductions. Permanently discontinue if unable to tolerate 20 mg/m²/dose.
  - Do not escalate dose after it has been reduced

Important notice: National Community Oncology Dispensing Association, Inc. (NCODA), has developed this Positive Quality Intervention platform. This platform represents a brief summary of medication uses and therapy options derived from information provided by the drug manufacturer and other resources. This platform is intended as an educational aid and does not provide individual medical advice and does not substitute for the advice of a qualified healthcare professional. This platform does not cover all existing information related to the possible uses, directions, doses, precautions, warning, interactions, adverse effects, or risks associated with the medication discussed in the platform and is not intended as a substitute for the advice of a qualified healthcare professional. The materials contained in this platform are for informational purposes only and do not constitute or imply endorsement, recommendation, or favoring of this medication by NCODA, which assumes no liability for and does not ensure the accuracy of the information presented. NCODA does not make any representations with respect to the medications whatsoever, and any and all decisions, with respect to such medications, are at the sole risk of the individual consuming the medication. All decisions related to taking this medication should be made with the guidance and under the direction of a qualified healthcare professional.
Co-pay Support

1. Private/commercial insurance:
   a. Consider patient enrollment in *Taiho Oncology Patient Support Co-pay Assistance Program* to reduce out-of-pocket expenses to $0
      i. [www.taihopatientsupport.com](http://www.taihopatientsupport.com)

2. Public/government insurance, (ex. Medicare, Medicaid)
   a. Consider utilizing *Extra-Help*, the Low-Income Subsidy (LIS) from Medicare program
      i. Financial assistance for patients who may otherwise be unable to afford the costs associated with their Medicare Part D plan
      ii. To learn more visit [https://secure.ssa.gov/i1020/start](https://secure.ssa.gov/i1020/start)
   b. Refer to nonprofit foundations or Patient Assistance Program (PAP)

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