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Beizray – An FDA-Approved Albumin Solubilized Formulation of Docetaxel

Description: The purpose of this PQI is to review the utility and practical considerations for use of albumin solubilized docetaxel (Beizray) in clinical practice**.**

Background[1-4]**:**

- Beizray is the first albumin-solubilized formulation of docetaxel that omits synthetic polysorbate 80, the excipient commonly implicated in development of docetaxel-related infusion reactions. Beizray does not contain other synthetic solvents such as PEG 300.
- Docetaxel binds to β-tubulin dimers inhibiting microtubule depolymerization, arresting the cell at G2/M phase of mitosis, and ultimately results in apoptotic cell death.
- Albumin is a natural carrier protein and has been shown to facilitate drug delivery to tumors via gp-60 and SPARC interactions[3]
- Beizray was approved by the FDA in October of 2024 via the 505(b)(2) pathway for the treatment of:
    - Breast Cancer (BC):
        - Single agent after chemotherapy failure for locally advanced/metastatic disease
        - Adjuvantly in combination with doxorubicin and cyclophosphamide for the treatment of operable, node-positive disease
    - Non-Small Cell Lung Cancer (NSCLC)
        - Single agent for advanced/metastatic NSCLC after platinum failure
        - Locally advanced/metastatic untreated NSCLC in combination with cisplatin for treatment-naïve patients
    - Metastatic castration-resistant prostate cancer (CRPC) in combination with prednisone
    - Untreated/advanced gastric/gastroesophageal junction cancer (GC) in combination with fluorouracil and cisplatin
    - Locally advanced squamous cell carcinoma of the head and neck (SCCHN) in combination with fluorouracil and cisplatin
- Studies evaluating Beizray report a reduced incidence of grade 3/4 hematologic toxicities (neutropenia, leukopenia, lymphopenia) and similar rates of infusion related reactions compared to reference docetaxel. However, existing studies of polysorbate 80–free docetaxel products have generally involved relatively small patient numbers and were not designed or powered to detect differences in incidence of hypersensitivity reactions.
- Most common adverse reactions across all Beizray indications are infections, neutropenia, anemia, febrile neutropenia, hypersensitivity, thrombocytopenia, neuropathy, dysgeusia, dyspnea, constipation, anorexia, nail disorders, fluid retention, asthenia, pain, nausea, diarrhea, vomiting, mucositis, alopecia, skin reactions, and myalgia

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PQI Process:

- Verify Correct Dosing[4]

Indication	Dose	Route & Duration	Frequency	Notes
BC Locally Advanced/Metastatic	60 – 100 mg/m^2	IV over 60 minutes	Every 3 weeks	
BC Adjuvant	75 mg/m^2	IV over 60 minutes	Every 3 weeks	Sequencing 1. Doxorubicin 2. Cyclophosphamide 3. Beizray
NSCLC (prior platinum)	75 mg/m^2	IV over 60 minutes	Every 3 weeks	
NSCLC (untreated)	75 mg/m^2	IV over 60 minutes	Every 3 weeks	Sequencing 1. Beizray 2. Cisplatin
CRPC	75 mg/m^2	IV over 60 minutes	Every 3 weeks	Used concomitantly with prednisone 5 mg PO BID
GC	75 mg/m^2	IV over 60 minutes	Every 3 weeks	Sequencing 1. Beizray 2. Cisplatin 3. 5-FU
SCCHN	75 mg/m^2	IV over 60 minutes	Every 3 weeks	Sequencing 1. Beizray 2. Cisplatin 3. 5-FU

- Review Patient Specific Factors[4]:
  - Baseline pregnancy test in female patients of reproductive age
  - Prior to the start of each cycle assess:
    - CBC
      - Hold administration until ANC $\geq$ 1500 cells/mm^3 and platelets $\geq$ 100,000 cells/mm^3
      - 25% dose reduction recommended following severe neutropenia (< 500 cells/mm^3) lasting 7+ days, febrile neutropenia, or grade 4 infection
    - CMP
      - Avoid the use of Beizray in patients with bilirubin > ULN or in patients with AST/ALT > 1.5X ULN + Alkaline Phosphatase > 2.5X ULN
      - For isolated elevations of transaminase > 1.5X ULN, consider dose modification
- Drug-drug interactions: docetaxel is a major CYP3A4 substrate; concomitant use of Beizray and drugs that inhibit CYP3A4 may increase exposure to docetaxel and should be avoided. Docetaxel is also a substrate of OATP1B1/1B3 and P-gp drug transporters
- Ensure Appropriate Prophylactic Medications Ordered[4,5]:
  - Dexamethasone for prevention of hypersensitivity reactions (HSRs) and fluid retention – Rx for dexamethasone 8 mg PO BID X3 days starting the day prior to Beizray sent to patient preferred pharmacy

        - May consider dexamethasone 8 mg PO at 12 hours, 3 hours and 1 hour prior to Beizray infusion for patients on concurrent prednisone therapy when used for the management of CRPC
        - May also consider use of dexamethasone 20 mg IV X1 prior to docetaxel infusions for patients non adherent to the above regimens
    - Antiemetics
        - Beizray is considered to have low emetic risk when utilized as a single agent
        - Use of a 5HT-3 receptor antagonist (RA), dexamethasone, or prochlorperazine oral or IV is an appropriate prophylaxis strategy in this context
        - When used in combination with doxorubicin + cyclophosphamide or cisplatin (high emetic risk agents), antiemetic prophylaxis should be escalated to one of the following:
            - Olanzapine + NK1 RA+ 5-HT3 RA + Dexamethasone
            - Olanzapine + Palonosetron + Dexamethasone
            - NK1 RA + 5HT3 RA + Dexamethasone
        - Consider prescription of PRN antiemetics for breakthrough nausea/vomiting
        - If cisplatin is utilized also ensure appropriate hydration orders are placed per institutional protocols
    - Growth Factor
        - GCSF prophylaxis may be considered for patients developing febrile or persistent neutropenia or neutropenic infection with Beizray administration
- Preparation/Administration[4]
    - Available as vial only and in a kit with 25% Albumin, 20 mg/mL concentration

Presentation	Beizray Component	Albumin Component
Beizray 160mg kit	Two single dose vials: 80mg / 4mL each	One single-dose vial: 50 mL of 25% Albumin Human USP solution for infusion
Beizray 80 mg kit	One single dose vial: 80mg / 4mL	One single-dose vial: 50 mL of 25% Albumin Human USP solution for infusion
Beizray 40 mg kit	Two single dose vials: 20mg / 1mL each	One single-dose vial: 50 mL of 25% Albumin Human USP solution for infusion
Beizray carton	One single dose vial: 20mg / mL or 80 mg/ 4 mL	Not included

    - Beizray must be diluted with 0.9% Sodium Chloride Injection (NS) to ensure a final concentration between 0.14 mg/mL and 0.31 mg/mL in the final infusion solution
    - Preparation steps:
        1. Calculate the amount of Beizray (mL) required for product preparation:
            - Calculate the patient and indication specific dose (ex. 75 mg/m2 X BSA 2m2= 150 mg) then divide by 20 mg/mL (ex. 150 mg/20= 7.5 mL)
        2. Determine the amount of NS Required

Calculated Amount of Beizray	Calculated Amount of Beizray (mg)	Size of NS Infusion Bag
≤ 4 mL	≤ 80 mg	250mL
> 4mL to ≤ 8.8 mL	> 80 mg to ≤ 176 mg	500 mL
> 8.8 mL	> 176 mg	1000 mL

3. Determine the amount of 25% Albumin Required
    - Required amount of Beizray (mL) X 6 = needed Albumin (mL) (ex. 7.5 mL X 6= 45 mL)
4. Withdraw the calculated amount of 25% Albumin from the vial and injection into the NS infusion bag, then thoroughly mix by inverting at least 5 times. Do not shake
5. Aseptically withdraw the previously calculated amount of Beizray and inject into the diluted albumin bag. Invert at least 10 times; do not shake
6. Visually inspect the final infusion solution for particulate matter or discoloration

Storage Conditions	Final Infusion Stability
2 – 8 °C (36 – 46 °F)	Stable for 24 hours
25 °C (77 °F)	Stable for 4 hours

Patient-Centered Activities[7-10]**:**

- Review medication list and discuss identified drug interactions
- Provide education on the duration, frequency and number of planned cycles of therapy
- Review potential ADEs with patient and provide reference material for future use
    - Docetaxel
    - Nausea/Vomiting
    - Diarrhea
    - Stomatitis
    - Fatigue
    - Alopecia
    - Dermatologic Toxicities

    - Infection
        - Patients should be instructed to monitor for and report new signs/symptoms concerning for infection
    - Edema/Effusions
        - Fluid retention typically occurs initially in the lower extremities and may become more generalized
        - Related to cumulative dose other risk factors include cardiac and renal comorbidities
        - Non-pharmacologic management strategies include compression stockings, salt-restriction, extremity elevation
    - CIPN
        - Presents as sensory and motor peripheral neuropathy in a stocking-glove distribution
        - Risk factors for development of neuropathy with docetaxel include cumulative dose > 300 mg/m^2 and older age
        - Symptoms are typically at least partially reversible but may be prolonged following discontinuation
    - HSRs
        - Use of Beizray is contraindicated in patients with prior hypersensitivity to docetaxel. Cross sensitivity may occur in patients with paclitaxel HSRs, use with caution in this setting.
        - HSRs typically occur with the first 1-2 infusions of docetaxel products
        - Characterized by flushing, rash/erythema, hypotension, dyspnea +/- bronchospasm
        - Management strategies for HSRs with docetaxel-based products include interrupting the infusion and administering supportive medications. Resumption of therapy at a

reduced rate may be considered upon resolution of symptoms. Consider use of prophylactic H1 & H2 blockers with subsequent infusions.

- Ensure patient understands administration instructions for dexamethasone and PRN antiemetics and has prescriptions available
- Request patient notify the oncology team for modifications to medication list

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