

BEIZRAY (*docetaxel*) infusion, for IV use
DOCIVYX (*docetaxel*) infusion, for IV use

PLEASE NOTE: Traditional generic IV Docetaxel does NOT require a Prior Authorization (PA).

PA Criteria	Criteria Details
<p>Description</p>	<p>Docetaxel is a microtubule inhibitor.</p> <p>BEIZRAY is a new formulation of docetaxel using human albumin for solubilization vs. traditional synthetic solvents (such as Polysorbate-80) that may be found in older docetaxel formulations.</p> <ul style="list-style-type: none"> • This formulation is said to cause fewer hypersensitivity reactions and has a lower alcohol content; reduced blood toxicities (e.g., febrile neutropenia). • CANNOT be substituted for or with other docetaxel products (different administration instructions and dosages). <p>DOCIVYX is a ready-to-use formulation that does NOT require dilution; simplifies administration process vs. traditional docetaxel.</p>
<p>Covered Uses (FDA approved indication)</p>	<p>Docetaxel is indicated for the treatment of:</p> <ol style="list-style-type: none"> a. Breast Cancer (BC): single agent for locally advanced or metastatic BC after chemotherapy failure; and with doxorubicin and cyclophosphamide as adjuvant treatment of operable node-positive BC b. Non-small Cell Lung Cancer (NSCLC): single agent for locally advanced or metastatic NSCLC after platinum therapy failure; and with cisplatin for unresectable, locally advanced or metastatic untreated NSCLC c. Castration-Resistant Prostate Cancer (CRPC): with prednisone in metastatic castration-resistant prostate cancer d. Gastric Adenocarcinoma (GC): with cisplatin and fluorouracil for untreated, advanced GC, including the gastroesophageal junction e. Squamous Cell Carcinoma of the Head and Neck (SCCHN): with cisplatin and fluorouracil for induction treatment of locally advanced SCCHN <p>The National Comprehensive Cancer Network® (NCCN) provides additional recommendations with a category 1, 2A level of evidence for the use of docetaxel:</p> <ol style="list-style-type: none"> a. Bladder cancer, including urothelial carcinoma of the bladder, primary carcinoma of the urethra, upper genitourinary (GU) tract tumors and urothelial carcinoma of the prostate b. Bone cancer, including Ewing’s sarcoma and osteosarcoma c. Breast Cancer d. Cervical Cancer e. Esophageal and esophagogastric junction cancer f. Gastric Cancer g. Head and Neck Cancer h. Non-small Cell Lung Cancer (NSCLC) i. Occult primary tumors – adenocarcinoma and squamous cell carcinoma j. Ovarian cancer, including fallopian tube cancer and primary peritoneal cancer k. Prostate Cancer l. Small Bowel Adenocarcinoma m. Small cell lung cancer (SCLC) n. Soft tissue sarcoma

	<ul style="list-style-type: none"> o. Thyroid carcinoma – anaplastic carcinoma in combination with doxorubicin p. Uterine neoplasms—in combination with gemcitabine or carboplatin q. Vaginal Cancer 																						
<p>Dosing and Administration</p>	<p>Dosing Regimen</p> <p>Administer in a facility equipped to manage possible complications (e.g., anaphylaxis).</p> <p>Administer IV over one hour every three weeks.</p> <ul style="list-style-type: none"> • BC locally advanced or metastatic: 60 mg/m² to 100 mg/m² single agent • BC adjuvant: 75 mg/m² administered 1 hour after doxorubicin 50 mg/m² and cyclophosphamide 500 mg/m² every three weeks for six cycles • NSCLC: after platinum therapy failure: 75 mg/m² single agent • NSCLC: chemotherapy naive: 75 mg/m² followed by cisplatin 75 mg/m² • CRPC: 75 mg/m² with 5 mg prednisone twice a day continuously • GC: 75 mg/m² followed by cisplatin 75 mg/m² (both on day one only) followed by fluorouracil 750 mg/m² per day as a 24-hr IV (days 1-5), starting at end of cisplatin infusion • SCCHN: 75 mg/m² followed by cisplatin 75 mg/m² IV (day 1), followed by fluorouracil 750 mg/m² per day as a 24-hr IV (days 1-5), starting at end of cisplatin infusion; for four cycles • SCCHN: 75 mg/m² followed by cisplatin 100 mg/m² IV (day one), followed by fluorouracil 1000 mg/m² per day as a 24-hr IV (days 1-4); for three cycles <p>For all patients:</p> <ul style="list-style-type: none"> • Premedicate with oral corticosteroids • Adjust dose as needed 																						
<p>Billing and Coding Information</p>	<table border="1" data-bbox="487 1199 1529 1430"> <thead> <tr> <th></th> <th>10-digit NDC</th> <th>11-digit NDC</th> </tr> </thead> <tbody> <tr> <td>BEIZRAY</td> <td>80 mg: 70710-2091-3 160 mg: 70710-2093-4</td> <td>80 mg: 70710-2091-03 160 mg: 70710-2093-04</td> </tr> <tr> <td>DOCIVYX</td> <td>20 mg: 83831-101-02 80 mg: 83831-102-08 160 mg: 83831-103-16</td> <td>20 mg: 83831-0101-02 80 mg: 83831-0102-08 160 mg: 83831-0103-16</td> </tr> </tbody> </table> <table border="1" data-bbox="487 1451 1529 1587"> <thead> <tr> <th></th> <th>HCPCS Code</th> <th>Description</th> </tr> </thead> <tbody> <tr> <td>BEIZRAY</td> <td>J9174</td> <td>Injection, docetaxel (BEIZRAY), 1 mg</td> </tr> <tr> <td>DOCIVYX</td> <td>J9172</td> <td>Injection, docetaxel (DOCIVYX), 1 mg</td> </tr> </tbody> </table> <table border="1" data-bbox="487 1608 1529 1707"> <thead> <tr> <th>CPT Procedural Codes</th> <th>Description</th> </tr> </thead> <tbody> <tr> <td>96413</td> <td>Chemotherapy IV infusion, up to one hour</td> </tr> </tbody> </table>		10-digit NDC	11-digit NDC	BEIZRAY	80 mg: 70710-2091-3 160 mg: 70710-2093-4	80 mg: 70710-2091-03 160 mg: 70710-2093-04	DOCIVYX	20 mg: 83831-101-02 80 mg: 83831-102-08 160 mg: 83831-103-16	20 mg: 83831-0101-02 80 mg: 83831-0102-08 160 mg: 83831-0103-16		HCPCS Code	Description	BEIZRAY	J9174	Injection, docetaxel (BEIZRAY), 1 mg	DOCIVYX	J9172	Injection, docetaxel (DOCIVYX), 1 mg	CPT Procedural Codes	Description	96413	Chemotherapy IV infusion, up to one hour
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<p>Product Availability</p>	<p>BEIZRAY:</p> <ul style="list-style-type: none"> a. BEIZRAY 80 mg kit consisting of the following: <ul style="list-style-type: none"> i. One single-dose vial of BEIZRAY: 80 mg/4 mL ii. One single-dose vial of IV Solution Stabilizer: 50 mL of 25% Albumin Human b. BEIZRAY 160 mg kit consisting of the following: <ul style="list-style-type: none"> i. Two single-dose vials of BEIZRAY: 80 mg/4 mL each ii. One single-dose vial of IV Solution Stabilizer: 50 mL of 25% Albumin Human <p>DOCIVYX: Single-dose vials</p> <ul style="list-style-type: none"> • 20 mg/2 mL • 80 mg/8 mL • 160 mg/16 mL
<p>Contraindications</p>	<ul style="list-style-type: none"> a. Hypersensitivity to docetaxel b. Neutrophil counts of <1500 cells/mm³
<p>Recommended Medical Monitoring</p>	<p>Black Box Warning – Toxic Deaths, Hepatotoxicity, Neutropenia, Hypersensitivity Reactions and Fluid Retention</p> <ul style="list-style-type: none"> a. Treatment-related mortality increases with abnormal liver function, at higher doses, and in patients with NSCLC and prior platinum-based therapy receiving docetaxel at 100 mg/m² b. Should not be given if bilirubin > ULN, or if AST and/or ALT > 1.5 x ULN concomitant with alkaline phosphatase > 2.5 x ULN. LFT elevations increase risk of severe or life-threatening complications. Obtain LFTs before each treatment cycle c. Should not be given if neutrophil counts are < 1500 cells/mm³. Obtain frequent blood counts to monitor for neutropenia d. Severe hypersensitivity, including very rare fatal anaphylaxis, has been reported in patients who received dexamethasone premedication. Severe reactions require immediate discontinuation of Docetaxel Injection and administration of appropriate therapy e. Contraindicated if history of severe hypersensitivity reactions to docetaxel or to drugs formulated with polysorbate 80 f. Severe fluid retention may occur despite dexamethasone <p>Docetaxel treatment is also associated with:</p> <ul style="list-style-type: none"> a. Acute myeloid leukemia b. Cutaneous reactions c. Neurologic reactions d. Asthenia e. Embryo-Fetal toxicity

Approval Criteria	<p>Traditional generic Docetaxel does NOT require a Prior Authorization (PA).</p> <p>For coverage to be approved for BEIZRAY or DOCIVYX, providers will need to demonstrate a medical-ly-necessary need to use these formulations over traditional Docetaxel.</p> <p>BEIZRAY – provider must demonstrate FDA approved indication, along with prior history of potentially serious adverse reactions associated with traditional Docetaxel infusion.</p> <p>DOCIVYX – provider must demonstrate FDA approved indication and medically necessary reason as to why traditional Docetaxel is not available or cannot be utilized.</p> <ul style="list-style-type: none"> Members must have prior history of hypersensitivity reactions and severe fluid retention with traditional Docetaxel infusion.
Age Restriction	Adults ≥ 18 years old
Coverage Duration	<p>Initial: six months. Reauthorization: 12 months.</p> <p>Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice.</p>
Other Criteria (LCD, NCD, etc.)	Must follow LCD L37205 – Chemotherapy Drugs and their Adjuncts
Misc Info, Appendix Etc.	None.

STATUS	DATE REVISED	REVIEW DATE	APPROVED/REVIEWED BY	EFFECTIVE DATE
Created	1/15/26	1/15/26	Tamara Chinarian, PharmD, Clinical Pharmacist	N/A
Approved	N/A	2/12/26	Pharmacy & Therapeutics (P&T) Committee	2/12/26