REQUEST FOR FORMULARY EXCEPTION OR PRIOR AUTHORIZATION FOR METASTATIC BREAST CANCER AGENT

Instructions for Healthcare Professionals:

Prescribers may complete this form and send it to their patient's insurer to request coverage of SOLTAMOX® (tamoxifen citrate) when it is not on the insurer's prescription drug formulary or if the plan requires prior authorization.[1]

Please consider the following when completing the form:

- It is important to clearly identify the rationale for the request based on your clinical judgment.
  - While the primary reason for prescribing SOLTAMOX may be to treat estrogen receptor-positive metastatic breast cancer or to reduce the risk of breast cancer in high-risk women, it will assist payers if your request includes a detailed description of why the patient should have access to SOLTAMOX. For example:
    - Failed trial(s) of other agent(s)
    - Contraindication to formulary or preferred agent
    - Currently being treated with SOLTAMOX
    - Another specified reason
- Consider attaching, if appropriate, documents that provide additional clinical information to support the request, such as:
  - Full prescribing information
  - Patient chart notes
  - Clinical guidelines
  - A front and back copy of the patient's prescription drug card
- Carefully review the form for completeness and accuracy before sending to the payer. Payers are likely to return incomplete forms to request additional documentation, which can delay their review of your request.
- A special word about expedited requests:
  - You can ask the payer for an expedited decision if you believe that waiting the amount of time for a standard decision could harm the patient's life, health, or ability to regain maximum function or if your patient is currently being treated with SOLTAMOX.

See Important Safety Information on page 3 and full prescribing information for SOLTAMOX at https://soltamox.com/.

Reference: 1. SOLTAMOX prescribing information. Mayne Pharma; June 2019.

FORMULARY EXCEPTION OR PRIOR AUTHORIZATION FOR METASTATIC BREAST CANCER AGENT

Patient Information

Patient's Name: Date of Birth: / /

Street Address:

City, State: Zip Code: Patient Phone Number:

Insurance Information

Name of Subscriber (if different than patient):

Patient Relationship to Subscriber: Subscriber Date of Birth: / /

Medical Insurance Plan Information **Plan Type (check one):** ◯ Commercial ◯ Exchange ◯ Medicaid ◯ Medicare ◯ Other

Payer Name: Member ID: Group Number:

Prescription Drug Plan Information Pharmacy Benefit Manager:

Prescription Drug Plan Name: Member ID: Group Number:

Prescriber Information

Prescriber's Name: Title: NPI #:

Clinic Name: Specialty:

Clinic Address:

City, State: Zip Code: Office Contact Name:

Office Contact Email Address: Office Contact Phone Number: Secure Fax Number:

Medication

Agent Name: SOLTAMOX® (tamoxifen citrate) 20 mg/10 mL solution (NDC 89141-123-01)[1]

☐ 20 mg per day for treatment of metastatic breast cancer

☐ 20 mg per day for adjuvant treatment of breast cancer or risk reduction in high risk women

☐ 40 mg per day in 2 divided doses for treatment of metastatic breast cancer

☐ Other dosing: _____

Medical Information (check applicable items)

Please specify the indication for use as documented in the medical record by checking the applicable ICD-10-CM diagnosis code(s) from the options below:

Treatment of adult patients with estrogen receptor-positive (ER+) metastatic breast cancer:

- ☐ C50.000 Z17.0 ER+ malignant neoplasm of nipple and areola of breast
- ☐ C50.100 Z17.0 ER+ malignant neoplasm of central portion of breast
- ☐ C50.200 Z17.0 ER+ malignant neoplasm of upper-inner quadrant of breast
- ☐ C50.300 Z17.0 ER+ malignant neoplasm of lower-inner quadrant of breast
- ☐ C50.400 Z17.0 ER+ malignant neoplasm of upper-outer quadrant of breast
- ☐ C50.500 Z17.0 ER+ malignant neoplasm of lower-outer quadrant of breast
- ☐ C50.600 Z17.0 ER+ malignant neoplasm of axillary tail of breast
- ☐ C50.800 Z17.0 ER+ malignant neoplasm of overlapping sites of breast
- ☐ C50.900 Z17.0 ER+ malignant neoplasm of breast of unspecified site

Risk reduction of invasive breast cancer following breast surgery or radiation in adult women with ductal carcinoma in situ (DCIS):

- ☐ D05.100 Intraductal carcinoma in situ of unspecified breast
- ☐ Z85.300 Personal history of malignant neoplasm of breast
- ☐ Y83.800 Other surgical procedures as the cause of abnormal reaction of the patient, or of later complication, without mention of misadventure at the time of the procedure
- ☐ Y84.200 Radiological procedure and radiotherapy as the cause of abnormal reaction of the patient, or of later complication, without mention of misadventure at the time of the procedure

To reduce incidence of breast cancer in adult women at high risk:

- ☐ Z85.300 Personal history of malignant neoplasm of breast
- ☐ Z80.300 Family history of malignant neoplasm of breast
- ☐ Z15.010 Genetic susceptibility to malignant neoplasm of breast
- ☐ Z79.810 Prophylactic drug therapy with selective estrogen receptor modulators
- ☐ Z79.811 Long-term (current) use of aromatase inhibitors
- ☐ Z79.890 Hormone replacement therapy

Rationale for Request

1. Is the patient currently treated or was previously treated with the requested medication? ☐ Yes ☐ No
2. Specify rationale for SOLTAMOX treatment and check any boxes that apply:

☐ Previously tried treatments – List medications:

☐ Contraindications ☐ Allergies ☐ Other reason(s):

3. **For expedited requests:** As the patient's healthcare provider, I am requesting that you expedite your determination on this request within 24 hours because (check one):

◯ Waiting for a standard decision could harm the patient's life, health, or ability to regain maximum function. ◯ The patient is undergoing a current course of treatment with SOLTAMOX.

I Certify That the Information Provided in This Form Is Accurate to the Best of My Knowledge

Healthcare Provider's Signature Date

Reference: 1. SOLTAMOX prescribing information. Mayne Pharma; June 2019.

INDICATIONS AND IMPORTANT SAFETY INFORMATION

WARNING: UTERINE MALIGNANCIES and THROMBOEMBOLIC EVENTS

- **Serious, life-threatening, and fatal events from use of tamoxifen include uterine malignancies, stroke, and pulmonary embolism.**
- **Discuss risks and benefits of tamoxifen with women at high risk for breast cancer and women with ductal carcinoma in situ (DCIS) when considering tamoxifen use to reduce the risk of developing breast cancer.**
- **For most patients already diagnosed with breast cancer, the benefits of tamoxifen outweigh its risks.**

See full prescribing information for complete boxed warning.

SOLTAMOX® Important Safety Information

- Tamoxifen citrate is contraindicated in patients who require concomitant warfarin therapy, or a history of deep vein thrombosis or pulmonary embolus, and in patients with known hypersensitivity to the drug or any of its ingredients.
- Uterine malignancies: Promptly evaluate abnormal vaginal bleeding in a woman with current or past tamoxifen use.
- Thromboembolic events: Risk increases with coadministered chemotherapy. For treatment of breast cancer, consider risks and benefits in patients with a history of thromboembolic events.
- Embryo-fetal toxicity: Can cause fetal harm. Advise females of reproductive potential of the potential risk to a fetus and to use effective contraception.
- Effects on the liver: Liver cancer and liver abnormalities, some fatal, have occurred. Perform periodic liver function testing.
- The most common adverse reactions (≥20% incidence) associated with tamoxifen are hot flashes, mood disturbances, vaginal discharge, vaginal bleeding, nausea, and fluid retention.
- Anastrozole and letrozole: Should not be used in combination with tamoxifen.
- Warfarin: Do not use in patients taking tamoxifen for DCIS and for reduction in breast cancer incidence in women at high risk. Closely monitor coagulation indices for increased anticoagulant effect when used with tamoxifen for metastatic breast cancer or as adjuvant therapy.
- Do not use tamoxifen in lactating women.
- Verify pregnancy status of females prior to initiation of tamoxifen.
- Advise females and males to use effective contraception.

Please see full Prescribing Information for SOLTAMOX®.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

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