

STEP 1: Complete Patient Information

EAP Patient: Yes No If Yes, Study Site: _____

Primary Language: English Other: _____

First Name: _____ **Last Name:** _____

Gender: Male Female **Date of Birth:** ____ / ____ / ____

Address: _____

City: _____ State: _____ Zip: _____

Home Phone: _____ **Cell Phone:** _____

Preferred Phone: Home Cell

Best Time to Contact: Morning Afternoon Evening

Email: _____

Alternate Authorized Contact Name: _____

Relation to Patient: _____ Contact Phone: _____

STEP 2: Complete Insurance Information

▶ Please include copies of the front and back of your patient's insurance card(s)

Referral to PAP / Patient Has No Insurance Medicaid Pending: Yes No

Primary Insurance:

ID #: _____ Group #: _____ Phone: _____

Subscriber Name: _____ DOB: _____

Subscriber Relationship to Patient: _____

Secondary Insurance:

ID #: _____ Group #: _____ Phone: _____

Subscriber Name: _____ DOB: _____

Subscriber Relationship to Patient: _____

Pharmacy Plan Name: _____

Policy #: _____ Group #: _____ Phone: _____

Employer: _____ Rx Bin #: _____ Rx PCN#: _____

● **STEP 3: Sign Patient Authorization:** Please include patient signature to provide services. [See page 2 of this form to read and sign the patient authorization.]

STEP 4: Complete Physician Information

Prescriber Name: (First, Last) _____

Facility/Practice Name: _____

Address: _____

City: _____ State: _____ Zip: _____

Office Contact:

Phone: _____ **Fax:** _____

Contact Email: _____

Specialty: _____ NPI #: _____

State Medical Lic #: _____ Tax ID #: _____

Payer-Specific ID #: _____ DEA #: _____

STEP 5: Select Provider Preferred Specialty Pharmacy

Accredo Avella Biologics CVS/Caremark

Onco360 Walgreens On site dispensing Other: _____

STEP 6: Complete Diagnosis & Clinical Information

Primary Diagnosis ICD 10 Code: _____

Clinical TNM stage: mCRC metastatic gastric cancer incl. GEJ Other

Line of Therapy: Third Fourth Fifth Other

Previous Treatment: None Surgery Radiation Chemo/Targeted Therapy:
 Please specify: FOLFOX FOLFIRI FOLFOXIRI CapeOx Irinotecan Capecitabine
 5-FU/LV bevacizumab cetuximab panitumumab regorafenib ziv-aflibercept
 pembrolizumab nivolumab ramucirumab trastuzumab Other: _____

Test Completion: EFGR Test Yes No Result _____

MSI-H Test Yes No Result _____

dMMR Test Yes No Result _____

HER-2 Test Yes No Result _____

KRAS Status: Wild Type Mutant

mCRC=metastatic colorectal cancer; GEJ=gastroesophageal junction.

STEP 7: Select Nursing Services (Must "opt in" if service needed)

Opt in Per discussion with patient, while on therapy, patient to receive nursing support to include education, compliance and general inquiries about therapy management.

STEP 8: Prescription Information (* Indicates field is required)

*Height: _____ *Weight: _____ *BSA (m²): _____

Rx LONSURF® (trifluridine and tipiracil)

Available in 15 mg and 20 mg tablets (based on the trifluridine component)

Take ____mg 2 times per day for days 1 through 5, then off for 2 days, then

Take ____mg 2 times per day for days 8 through 12, then off for 2 days. Rest 14 days.

SIG: _____

tablets per cycle: 15 mg: _____ 20 mg: _____ Refills: _____

STEP 9: Read and Sign Statement of Medical Necessity

By signing below, I certify that [a] the above-prescribed therapy is medically necessary, and [b] (check one):

- I have received from the patient identified above, or his/her personal representative, the necessary authorization to release, in accordance with applicable federal and state privacy laws and regulations, referenced medical and/or other patient information relating to the need for the above-prescribed therapy, to Taiho and its agents or contractors for the purpose of seeking information related to coverage for the therapy and/or assisting in initiating or continuing therapy.
- I have read and agree to the Business Associate Agreement on page 4 of this form.
- I authorize Taiho and its agents or contractors to forward a prescription for LONSURF, by fax or other mode of delivery, to a pharmacy within the Taiho Oncology Patient Support network.

▶ The physician is to comply with his/her state specific prescription requirements such as e-prescribing, state specific prescription form, fax language, etc. Non-compliance of state specific requirements could result in outreach to the prescriber.

Prescriber Signature: _____ Date: _____
 (no stamps) (Substitution Permitted)

Prescriber Signature: _____ Date: _____
 (no stamps) (Dispense As Written)

Patient Name: (First, MI, Last)

Date of Birth:

● Patient Authorization

A patient authorization is required to proceed with services. Please read and sign the patient authorization below.

I verify that the information provided herein is true and correct. I understand that the collection, use and disclosure of my personal health information (including but not limited to name, address, social security number, telephone number, insurance information, medical condition, medical records and other information contained on this form) is protected by law. By signing this authorization, I understand I agree to the collection, disclosure and use of my personal health information as described below.

I authorize each of my health plans, insurers, physicians, health care professionals, hospitals, clinics, pharmacies or other health care providers and those working on their behalf to disclose my personal health information to Taiho Oncology, Inc. ("Taiho"), its employees, affiliates and their representatives, agents and contractors for the following purposes: (i) investigating and resolving insurance coverage or reimbursement inquiries or reviewing eligibility for patient assistance programs, co-pay assistance or similar programs and enrolling me in such programs, (ii) contacting and providing my personal health information to my insurer, patient advocacy organizations, patient assistance programs or other funding sources to determine eligibility for coverage or other funds, (iii) fulfilling and coordinating prescription fulfillment and delivery, (iv) assisting with product training and providing product support and educational materials; and (iv) any internal use by Taiho. I understand that my information disclosed under this authorization may be re-disclosed by Taiho and may no longer be protected by federal or state privacy laws. I understand that I may refuse to sign this authorization, and my treating providers and health plans may not condition current or future treatment, payment or eligibility for benefits on my provision of this authorization. I understand that I am entitled to a copy of this authorization. I understand that I may cancel this authorization at anytime by mailing a letter requesting such cancellation to Taiho Oncology, Inc., P.O. Box 30226, Bethesda, MD 20824, but that this cancellation will not apply to any information already used or disclosed through this authorization. This authorization expires five (5) years from the date signed below.

I understand that my pharmacy providers may receive remuneration for disclosing my personal health information pursuant to this authorization. I further authorize my pharmacy providers to use my personal health information to communicate with me about the drug that has been prescribed for me and understand that they may receive a fee for such communications.

X Patient or Patient's Representative Signature:

Date:

If representative, relationship to patient (spouse, legal guardian, etc.) :

Patient Name: (First, MI, Last)

Date of Birth:

● Patient Assistance Program

Number of People in Your Household, Including You? 1 2 3 4 5 6 7 8+

What Is Your Total Annual Household Income? (Including SSI, gross wages, etc.) \$ _____

▶ To verify the above, you will need to provide one of the following: (1) copies of federal tax returns or other documents like bank statements, proof of Social Security Income, etc. or (2) authorization to obtain your credit profile from Experian Health for the purposes of verifying your income eligibility. **Please choose which option you prefer:**

You understand that by checking the I Agree box immediately following this notice, you are providing 'written instructions' to Taiho Oncology, Inc ("Taiho") and/or their agents under federal and/or state law authorizing electronic income verification by obtaining information from your personal credit profile or other information from Experian Health.

You authorize Taiho and/or their agents to obtain such information solely to validate your income eligibility for the purposes of determining your eligibility for patient assistance.

- I AGREE** to the terms above for electronic income verification using Experian Health
- I DO NOT AGREE** with the terms above and do not wish to have my income verified by Experian Health. I understand that I will be asked to provide supporting documentation to authenticate my income and eligibility

I attest that the above information is complete and accurate. I attest that I have no or insufficient prescription insurance coverage for the indicated medication, including Medicaid, Medicare or any other public or private program and I have insufficient financial resources to pay for the prescribed therapy.

I understand and agree that PAP medication received will not count toward my true-out-of-pocket costs (TROOP) as defined under the Medicare Modernization Act. I understand that the PAP medication will be prescribed to me by my physician and is provided at no charge to me or any other party; therefore, I agree that I will not submit any claim for the PAP medication to any third party, including my Medicare Part D Plan. I further agree that I will seek no reimbursement for any drug(s) obtained under this program.

By my signature, I authorize the release of the information about me and my medical condition to Taiho Oncology, Inc. ("Taiho") and/or their agents. I authorize Taiho and/or their agents to use and disclose such information for the assessment of my eligibility for and enrollment and administration of Taiho patient assistance, which may include contacting my insurer, public funding programs, social workers, advocacy organizations, healthcare providers, or other persons or entities Taiho may deem appropriate to release all medical records or requested information bearing on my eligibility to and benefits under the program.

Additionally, I agree that at any time during my enrollment, Taiho may request additional documentation to authenticate the statements made on my application. Taiho and/or their agents agree to not disclose any information to any third party except those required for program administration as authorized by me or as required by law. I understand and acknowledge that this assistance is temporary and that this program may be changed or discontinued at any time without notice. The information above will append the incomplete information provided on my original enrollment application.

Patient or Representative Signature: _____

Date: _____

If representative, relationship to patient (spouse, legal guardian, etc.): _____

Business Associate Agreement

Business Associate Agreement

Dear Doctor,

Taiho Oncology Patient Support would like to expedite the benefits investigation and triage of your prescriptions to get your patients on therapy as quickly as possible. Sometimes obtaining a Patient Authorization, found on page two, can delay obtaining treatment if the patient is not in your office to sign the form when you make the referral. Therefore, we are offering the opportunity for you to sign a Business Associate Agreement (BAA) with CareMetx, the firm that is operating Taiho Oncology Patient Support services. This BAA is an interim step that will allow CareMetx to initiate a benefits investigation and triage your prescriptions **for all your patients** as soon as possible to support access to treatment – while working in parallel to obtain the patient authorization – thus optimizing all the services for your patients on therapy.

– Taiho Oncology Patient Support

CareMetx (Company) is a Business Associate of the signatory physician (MD) in order to perform benefit investigation services, and other support services to patients, including services to assist in the timely filling of prescriptions (“Services”) for the MD. MD and Company agree that until permission is revoked by MD, Company shall perform such services for MD’s patients subject to the following terms. Company will use protected health information (PHI) only to provide the Services. Company will not use or further disclose PHI other than as permitted herein or as required by law. Company may use PHI from MD if necessary for the proper management and administration of Company or to carry out the legal responsibilities of Company. Company may de-identify the PHI. Once PHI is de-identified, it is no longer covered by this agreement. Company will implement appropriate safeguards to prevent unauthorized use or disclosure of PHI, including implementing requirements of the HIPAA Security Rule. Company will report to the MD any unauthorized use or disclosure of PHI, including any Security Incident that compromises the integrity of the PHI held by Company on behalf of MD and any Breach of PHI. Company will respond, in a manner to allow MD to comply with the requirements of the Privacy Rule, to requests from MD to provide individuals with access to their PHI. MD may require Company to make available PHI for amendments (and incorporate any required amendments) and accountings. Company will comply with the requirements of the Privacy Rule applicable to Company. Upon request by HHS or MD, Company will make available to HHS its internal practices, books, and records relating to the use and disclosure of PHI received from, or created or received by Company on behalf of MD for purposes of HHS determining MD’s or Company’s compliance with the HIPAA Privacy Rule. Upon termination of providing services to MD, Company shall return or destroy all PHI received from MD or created or received by Company unless such return or destruction is not feasible in which case Company shall extend these protections to PHI maintained by Company after the termination of this agreement. Company will ensure that its subcontractors who have access to PHI must agree to equivalent restrictions and conditions on PHI that apply to Company. MD may terminate its agreement with Company for violation of a material term, and contracts between Company and business associate subcontractors are subject to these same requirements. By signing this form, MD agrees to these business associate provisions.

X Prescriber Signature: _____

Date: _____

X CareMetx Signature: *Greg Lahens, CareMetx Privacy Officer*