Medi-Cal Benefit Request:
Biomarker and Pharmacogenetic Testing

Part I – Background:

The Department of Health Care Services (DHCS) oversees California's federal Medicaid program (called Medi-Cal). Medi-Cal offers no-cost and low-cost health coverage to eligible individuals who live in California. Medi-Cal covers most medically necessary care, which includes doctor and dentist appointments, prescription drugs, vision care, family planning, mental health care, drug or alcohol treatment, and biomarker and pharmacogenetic testing, as defined below.

DHCS' Benefits Division (BD) is responsible for setting medical coverage and reimbursement policy for most health care services provided by Medi-Cal. Please note that BD is not primarily responsible for developing coverage policy for family planning benefits and services (except for abortion services), specialty mental health (SMH) and substance use disorder (SUD)/Drug Medi- Cal Organized Delivery System (DMC-ODS) services provided through the county behavioral health delivery system, outpatient drugs, including physician administered drugs (PADs), blood factors, optometry, enteral nutrition, eyeglasses/fabrication, or medical supplies. Additionally, BD does not oversee coverage policy for the following specialty programs: California Children's Services (CCS) Program, Family Planning, Access, Care, and Treatment (FPACT) Program, Breast and Cervical Cancer Treatment Program (BCCTP), or Genetically Handicapped Persons Program (GHPP).

Part II – Definitions:
For purposes of this request, please note the following definitions:

- **"Medical necessity" or "medically necessary"**, pursuant to California Welfare and Institutions (W&I) Code section 14059.5, is defined as follows:
    - For individuals 21 years of age or older, a service is "medically necessary" or a "medical necessity" when it is reasonable and necessary to protect life, to prevent significant illness or significant disability, or to alleviate severe pain.
    - For individuals under 21 years of age, a service is "medically necessary" or a "medical necessity" if the service meets the standards set forth in Section 1396d(r)(5) of Title 42 of the United States Code.
        - As specified in Medi-Cal policy, Early and Periodic Screening, Diagnostic and Treatment (EPSDT) services are medically necessary or a medical necessity if they correct or ameliorate defects and physical and mental illnesses and conditions discovered through screening.
- **"Biomarker testing",** pursuant to W&I Code section 14132.09, is defined as the analysis of an individual's tissue, blood, or other biospecimen for the presence of a biomarker, including, but not limited to, "single-analyte tests, multiplex panel tests, and whole genome sequencing.
- **"Pharmacogenetic testing",** pursuant to W&I Code section 14132.108, is defined as

laboratory genetic testing that includes, but is not limited to, a panel test, to identify how a person's genetics may impact the efficacy, toxicity, and safety of medications.

Part III – Process:

When BD is making determinations about medical coverage and reimbursement policy for biomarker and pharmacogenetic testing under Medi-Cal, BD's clinical consultants first consider the following:

- Under W&I Code section 14132.09, whether the biomarker test in question meets any of the following:
    - A labeled indication for a test that has been approved or cleared by the United States Food and Drug Administration (FDA) or is an indicated test for an FDA-approved drug.
    - A national coverage determination made by the federal Centers for Medicare and Medicaid Services (CMS), to the extent allowed under the Medicaid program.
    - A local coverage determination made by a Medicare Administrative Contractor for California.
    - Evidence-based clinical practice guidelines, supported by peer-reviewed literature and peer-reviewed scientific studies published in or accepted for publication by medical journals that meet nationally recognized requirements for scientific manuscripts and that submit most of their published articles for review by experts who are not part of the editorial staff.
    - Standards set by the National Academy of Medicine.
- Under W&I Code section 14132.108 for pharmacogenetic testing, whether the pharmacogenetic test in question is supported by evidence-based clinical practice guidelines.

Once a determination is made to cover (i.e., make a benefit) a certain biomarker or pharmacogenetic test, BD's clinical consultants then establish specific criteria and requirements for coverage, which include utilization management controls, such as diagnosis code restrictions, frequency limits, prior authorization requirements, and more, to ensure medical necessity is satisfied. In developing specific coverage criteria and requirements, BD's clinical consultants – in partnership with other clinical consultants throughout DHCS – conduct an independent analysis and consider a myriad of factors, including, but not limited to: coverage determinations from other payors, including other state Medicaid programs; coverage determinations for federal Medicare, commercial insurance, etc.; guidance from federal oversight/policy bodies such as the Federal Food and Drug Administration, etc.; and evidence-based, nationally recognized clinical practice guidelines, and consensus statements; and peer-reviewed literature and randomized, controlled clinical studies/trials.

Please note that if BD determines it is appropriate to add the requested biomarker or pharmacogenomic test as a Medi-Cal benefit, BD will share this information with our colleagues in the

Fee-for-Service Rates Development Division (FFSRDD) to establish a Medi-Cal fee-for-service (FFS) reimbursement rate. Until a Medi-Cal FFS reimbursement rate is established, the billing code associated with the specific biomarker or pharmacogenomic test will be priced “by report” , whichmeans DHCS contracted fiscal intermediary will manually price any submitted claims based upon supporting documentation submitted by the Medi-Cal enrolled, billing provider. . Information about how to submit claims priced by report is available in the Medi-Cal Provider Manual.

Part IV – Instructions & Additional Information:

This Medi-Cal Benefit Request: Biomarker and Pharmacogenetic Testing (MBR-BPT) form must be completed by any external parties (e.g., providers, manufacturers, advocates, etc.) who are requesting BD’s consideration for adding a particular biomarker or pharmacogenetic test and/or billing code as a Medi-Cal benefit. External parties must also ensure that any required supporting documentation or information is submitted, as specified in more detail below. The completed MBR-BPT and any supporting document or information must be submitted to BD via email to dhcsmedicalpolicy@dhcs.ca.gov. Please note that failure to submit or fully complete the MBR-BPT along with any necessary supporting documentation or information may result in your MBR-BPT being returned and your request not being evaluated.

Depending on the nature of your coverage request, BD may need to consult with other DHCS divisions, which can increase the time needed to complete our review; however, on average, BD takes approximately one (1) month to complete its comprehensive analysis of the information provided on the MBR-BPT and conduct its own independent research before responding via email. Additionally, please note that if your coverage request would require additional state and/or federal approvals for BD to implement (e.g., the particular device, test/procedure, or service does not fall under an existing benefits coverage category), BD may be unable to issue a final benefits coverage decision and you would be informed via email.

Part IV – MBR-BPT:

Please complete items #1-9 and provide supporting documentation or information as requested. Please note that supporting documentation or information must either be submitted as a hyperlink and/or be attached as a separate file and submitted with the MBR Form via email to BD.

Please note that the MBR-BPT and anything supporting documentation submitted is subject to disclosure pursuant to the Public Records Act (PRA) (see Government Code section 6250 et seq.). As a result, BD recommends that requestors not submit any confidential or proprietary information. For more information on the PRA, please see DHCS’ Public Records Act website.

1. (a) Please provide the name and a brief description of the biomarker or pharmacogenetic test for which Medi-Cal coverage is being requested and/or where change (e.g., adjusting frequency limits, etc., removing prior authorization, etc.) in existing Medi-Cal policy is being requested.

(b) If the test is a biomarker test, as defined in Section II – Definitions, please indicate whether it meets one or more of the following:
biomarker tests that meet any of the following:

☐ A labeled indication for a test that has been approved or cleared by the United States Food and Drug Administration (FDA) or is an indicated test for an FDA-approved drug.

- If so, please identify and provide a link:

☐ A national coverage determination made by the federal Centers for Medicare and Medicaid Services (CMS), to the extent allowed under the Medicaid program.

- If so, please identify and provide a link:

☐ A local coverage determination made by a Medicare Administrative Contractor for California.

- If so, please identify and provide a link:

☐ Evidence-based clinical practice guidelines, supported by peer-reviewed literature and peer-reviewed scientific studies published in or accepted for publication by medical journals that meet nationally recognized requirements for scientific manuscripts and that submit most of their published articles for review by experts who are not part of the editorial staff.

- If so, please identify and provide a link to each applicable evidence-based clinical practice guidelines:

☐ Standards set by the National Academy of Medicine (NAM).

- If so, please identify and provide a link:

2. Please identify the specific billing code(s) (e.g., CPT or HCPCS code(s)) that will be used for the biomarker or pharmacogenetic test. If it is a proprietary laboratory code (e.g., a PLA code) specific to the device, test/procedure, or service, please specifically note that in your response. Please attach any documentation with the billing code description to your MBR-BPT.

3. Please provide a narrative overview of the clinical/medical effectiveness, which should include reference to applicable clinical guidelines, generally accepted standard of care, and to what extent – if any – there may be a reduction in risk and/or potential for improved health outcomes when compared to other available treatment options currently covered by Medi-Cal. For any requests to modify existing policy requirements, such as those related to frequency and/or prior authorization, please also provide an explanation as to why this is necessary and in alignment with applicable clinical guidelines. Please include copies of any referenced clinical guidelines with your MBR-BPT.

4. Please provide the date of federal Food and Drug Administration (FDA) clearance, including approvals and indications. Please include a copy of all FDA supporting documentation as an attachment with your MBR-BPT Form.

5. Please briefly describe the outcomes/conclusions of any peer-reviewed scientific literature and any randomized, controlled clinical studies/trials. For any requests to modify existing policy requirements, such as those related to frequency and/or prior authorization, please also provide an explanation as to why this is necessary and any published outcomes/conclusions that support your requested modification. Please include a complete (not summary) copy of each item referenced as an attachment with your MBR-BPT.

6. Please provide information on coverage determinations, such as detailed published policies, from other payors, including commercial insurance/health plans, other Medicaid programs, federal Medicare (including national/local coverage determinations), etc.

7. Please provide manufacturer invoice/cost information, any reimbursement rates from other state Medicaid programs or commercial insurers, and a cost comparison to other available treatment options currently covered by Medi-Cal. Please include any manufacturer invoice/cost sheets or other supporting documentation with your MBR-BPT.

8. Please provide any other information or supporting documentation that you believe would help BD make its final benefits coverage decision.

9. Please identify an appropriate contact, including both a phone number and email address, that BD can reach out to in case we have any questions or need further clarification.

Contact Name	Contact Phone Number	Contact Email Address