

VIVIO Health, Inc.

SUMMARY PLAN DOCUMENT

E. & J. Gallo Winery

This **SUMMARY PLAN DOCUMENT** is for your specialty drug plan (“Program”). This Program is separate from your pharmacy and medical benefit plans.

This Program provides you with coverage for certain specialty drugs. The list of managed drugs is available at the following URL: www.myvivio.com/gallo.

This Program does not include a network of pharmacies or providers. You will be directed to use a specific pharmacy or provider that has agreed to accept the Program’s offered pricing for Managed Drugs. The use of any other pharmacy or provider generally will not be reimbursed.

SECTION 1.

Glossary of Prescription Drug Terms

In this document you will see several key terms, which are defined below:

1.1 Managed Drug

A specialty prescription drug that is listed on URL provided above. Benefits for Managed Drugs are only available through this Program and are not Managed by any other offering of E. & J. Gallo Winery group health plan. The Managed Drugs list may also contain specialty drugs for which coverage is excluded for clinical, financial or plan design reasons.

1.2 Program

The specialty drug program offered by the sponsor which is administered by VIVIO.

SECTION 2.

Qualification for Program Benefits

2.1 Terms of Specialty Drug Coverage

To be eligible for coverage under the Program, the drug must be prescribed by a licensed prescriber who is qualified to evaluate and treat the disease or condition for which the drug is prescribed. Qualification to prescribe Managed Drugs does not require the prescriber to hold any specific Board certification; however, a determination of appropriateness by the Program may include a review of the physician’s competency to treat your condition and prescribe a Managed Drug.

The Program only covers certain drugs approved by the FDA for marketing and use in the USA. Since the FDA does not have objective standards on efficacy and effectiveness of drug therapies, determinations of investigational or experimental classification are made by VIVIO using their proprietary algorithms and methods. Medical foods that are voluntarily filed with the FDA are not covered. Drugs, biologics or cellular-based therapies that are approved or licensed with only orphan, breakthrough or limited population pathway designations are generally not covered due to the fact that these approvals were based on lower standards of evidence than a standard approval and may be excluded until their manufacturer provides data from additional randomized controlled trials.

2.2 Separate Program from Plan Sponsor’s Medical Benefits and Prescription Drug Benefits

The VIVIO Program is separate from the network arrangement of this Plan’s Medical Benefits and Prescription Drug Benefits. Plan participants are automatically enrolled in VIVIO Program coverage when enrolling in medical coverage under this Plan. Specialty drugs on the VIVIO coverage list are only covered through the VIVIO Program whether administered at home, pharmacy, physician office, ambulatory center or other outpatient location.

2.3 How Coverage Decisions Are Made

Authorization is required for all Managed Drugs unless this requirement is specifically waived by the Program. The Program will contact your prescribing physician to initiate the VIVIO therapy planning process. Any authorization that is issued as a result of the therapy planning process may be specific to a pharmacy, provider, a period of time, dosing frequency, maximum dose quantity, reimbursement limits, outcome measurements, and/or specific warranties required of the drug manufacturer.

The Program may make its coverage determination using any combination of the following methods; 1) a documented medical coverage policy, 2) externally referenceable standards of clinical practice, 3) clinical trial data supplied by manufacturers, or 4) disease specific clinical models developed by VIVIO. Coverage may only be provided for a preferred

drug for the treatment of your condition, or, your physician may be required to provide data to prove that a preferred drug is not appropriate for the treatment of your condition before another drug may be considered for coverage. In addition, the Program will require ongoing disease activity measures to assess whether ongoing therapies are effective in moving toward remission or managing disease progression.

VIVIO uses its proprietary dynamic market-based reference pricing model to set fair market value for the drugs acquired on behalf of the Employer sponsored plan. Generally, VIVIO considers manufacturer sponsored program(s) such as copay assistance, and other similar programs as reductions to the price of the drug, lowering its fair market value. When such programs exist, VIVIO reference prices a drug to a maximum of 50% of the drug cost until those discounts are exhausted. VIVIO does not consider any costs that are above fair market value in the accumulation of deductibles, coinsurance, copay or out-of-pocket maximums. VIVIO may also use other factors such as pricing of alternative therapies, clinical trial and real-world effectiveness data in its price computation algorithms.

2.4 Non-Duplication of Benefits

Non-duplication of benefits applies to Managed Drugs under this Program. When benefits are provided for a Managed Drug through this Program, the same drug is not Managed by any other offering of E. & J. Gallo Winery health benefit plan, even if the Program denies coverage for the drug.

2.5 Pre-certification Requirement

All VIVIO covered specialty drugs must be pre-certified through VIVIO.

2.6 Benefit Exclusions

- Drugs used in a clinical trial
- Experimental and/or Investigational drugs
- Non-Participating Pharmacy (Pharmacies not identified for usage through the VIVIO Program.)
- Not medically necessary

SECTION 3.

How You Can Obtain Specialty Drugs

3.1 Obtain Specialty Drugs

Contact VIVIO to obtain a Managed Drug through the Program using the information below under “Program Contact Information.”

SECTION 4.

What You Pay for Managed Drugs

4.1 Out of Pocket Costs

Your share of the cost for Managed Drugs may vary based on our proprietary dynamic pricing model. Often drug manufacturers offer programs to offset out of pocket expenses. The Program encourages the use and will help facilitate their use to help reduce the member's out of pocket expenses.

If you pay for a drug “out of pocket”, at a pharmacy other than the one you are directed to by the Program, you may not be reimbursed for your expense.

SECTION 5.

Day Supply and Refill Limits

5.1 Day Supply and Refill Limits

Specialty Drugs are subject to a “per fill” days’ supply limit that will not exceed a 30-day supply of medication, except by special request or as clinically necessary. The supply quantity for each prescription fill is determined by the dosing instructions that are included on the physician’s prescription. In most cases, it is required that you have not more than a seven-day supply of medication on hand before your prescription can be refilled.

SECTION 6.

Appeals Process

6.1 Appeals Process

Your plan offers you an appeals process if you have been denied care. You may call VIVIO for details at 1-800-470-4034 or find the details at MyVIVIO.com/gallo.

If you or your physician requests an appeal and additional information is provided, it is reviewed and evaluated by the VIVIO appeals unit to determine if the drug use meets coverage conditions specified or intended by your employer according to the procedures set forth below:

- Level 1:** The VIVIO Appeals Unit
- Level 2:** The VIVIO Appeals Unit or external third-party review organization
- Level 3:** Review by Independent Review Organization (IRO)

Appeal procedures apply to appeals of adverse benefit determinations of appropriateness, effectiveness and experimental classification of a specialty drug therapy. Appeals related to eligibility to participate in the plan are coordinated by your employer.

SECTION 7. Program Contact Information

VIVIO

Concierge:	1-800-470-4034
Fax:	1-888-677-6754
Program Website:	MyVIVIO.com
Email:	concierge@MyVIVIO.com