# SUMMARY OF MATERIAL MODIFICATIONS TO THE MOHAWK ESV, INC. HEALTH AND WELFARE BENEFIT PLAN

## Employer Identification Number 20-1880191 Plan Number 501

**Formal Document.** This Summary of Material Modifications ("SMM") amends and supplements the Summary Plan Descriptions ("SPDs") for the medical and prescription drug benefit programs offered under the Mohawk ESV, Inc. Health and Welfare Benefit Plan ("Plan"). This is a formal document that you should keep with your SPD and previous supplements for easy reference.

**Purpose of SMM.** This SMM notifies you of changes that have been made to the provisions of the Plan described in the SPD previously given to you. The terms of this SMM replace the terms of the previously or simultaneously distributed SPD wherever the terms may differ.

#### Specialty Prescription Drug Benefits Administered by VIVIO

Effective January 1, 2022, the specialty prescription drug benefits offered under the Plan will be managed by VIVIO. Express Scripts will continue to be the claims administrator for all prescription drug claims other than those involving specialty medications.

## **Qualification for Specialty Drug Benefits**

## Terms of Specialty Drug Coverage

The Plan provides you with coverage for certain specialty drugs. The list of specialty drugs covered by the Plan is available at mymohawkbenefits.com (see the "Specialty Drug List").

To be eligible for coverage under the Plan, a specialty 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 specialty drugs does not require the prescriber to hold any specific board certification; however, a determination of appropriateness by the Plan may include a review of the physician's competency to treat your condition and prescribe a specialty drug.

The Plan 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.

Prescription medications on the Plan's Specialty Drug List are only covered through the VIVIO program, whether administered at home, pharmacy, physician office, ambulatory center or other outpatient location.

**Please Note:** The Plan does not include a network of pharmacies or providers for specialty medications. Instead, you will be directed by VIVIO to use a specific pharmacy or provider that has agreed to accept the Plan's offered pricing for specialty drugs. The use of any other pharmacy or provider for specialty medications will not be reimbursed by the Plan.

#### How Coverage Decisions Are Made

Authorization is required for all specialty drugs unless this requirement is specifically waived by the Plan. The Plan 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 Plan may make its coverage determination using any combination of the following methods; (i) a documented medical coverage policy, (ii) externally referenceable standards of clinical practice, (iii) clinical trial data supplied by manufacturers, or (iv) 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 Plan will require ongoing disease activity measures to assess whether ongoing therapies are effective in moving toward remission or managing disease progression.

#### **Therapy Costs**

VIVIO uses its proprietary dynamic market-based reference pricing model to set fair market value for the drugs acquired on behalf of the Plan. Generally, VIVIO considers manufacturer sponsored programs 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.

A participant can only accumulate out-of-pocket costs for specialty drug therapies using the VIVIO program. Any direct reimbursement for out-of-pocket costs for a specialty drug by that drug's manufacturer or affiliated company provided to the participant is considered outside of and a violation of the VIVIO program. If such reimbursement is accepted by the participant, then no portion of the drug will be covered by the Plan, and if any portion was paid, the participant must reimburse any Plan paid portions.

#### Non-Duplication of Benefits

Non-duplication of benefits applies to specialty drugs under this Plan. When benefits are provided for a specialty drug through the Plan, the same drug will not be covered by any other portion of the Plan, even if VIVIO denies coverage for the drug.

#### Pre-certification Requirement

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

#### Benefit Exclusions

The Plan does not provide coverage for the following specialty drugs:

- Drugs used in a clinical trial
- Experimental and/or investigational drugs
- Pharmacies not identified for usage through the VIVIO program
- Drugs that are not medically necessary

## **How You Can Obtain Specialty Drugs**

Contact VIVIO at 1-800-470-4034 or <u>concierge@myvivio.com</u> to obtain a specialty drug through the VIVIO program.

#### What You Pay for Specialty Drugs

Your share of the cost for specialty drugs may vary based on VIVIO's proprietary dynamic pricing model. Often drug manufacturers offer programs to offset out of pocket expenses. The Plan encourages their use and will help facilitate their use to help reduce the participant'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 VIVIO, you will not be reimbursed for your expense by the Plan.

#### **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.

#### **Discretionary Authority**

The Plan Administrator has delegated to VIVIO its complete discretionary authority to interpret and apply Plan terms and to make factual determinations in connection with its review of internal benefit claims and appeals involving specialty medications.

Such discretionary authority is intended to include, but is not limited to, the determination of whether a person is entitled to benefits under the Plan, and the computation of any and all benefit payments. The Plan Administrator has also delegated to VIVIO (with respect to prescription drug claims involving specialty medications) its complete discretionary authority to perform a full and fair review, as required by ERISA, of each claim denial which has been appealed by the claimant or his duly authorized representative. VIVIO has the full extent of the Plan Administrator's discretionary authority and duties with respect to those responsibilities delegated to it, including full discretionary authority to interpret the Plan; determine eligibility for and the amount of

benefits under the Plan, including the discretionary authority to grant or deny internal claims and appeals; and exercise all of the power and discretionary authority contemplated by ERISA with respect to making initial claim and final internal appeal determinations under the Plan. VIVIO has the necessary discretionary authority and control to require deferential judicial review. Therefore, VIVIO's exercise of discretion in its interpretation of the Plan's written terms and its finding of fact in its role as the Plan's claims fiduciary will not be overturned unless a court determines they are arbitrary and capricious.

#### **Claims and Appeals**

Initial claims for specialty prescription drug benefits must be submitted to VIVIO by calling 1-800-470-4034 or emailing <u>concierge@myvivio.com</u>.

Internal appeals of denied specialty prescription drug claims must be submitted to:

VIVIO Health Appeals Unit Fax: 1-888-677-6754

Email: concierge@myvivio.com

The Plan's specialty drug program provides for two <u>mandatory</u> levels of internal appeal. This means that you must complete the Plan's second level of internal appeal to exhaust the Plan's administrative claim and appeal procedures with respect to your specialty drug claim. If your initial internal appeal is denied, you will have <u>90 days</u> to submit a request for a second level of internal review to the VIVIO Health Appeals Unit. Failure to comply with this important deadline will cause you to forfeit any right to any further review of an adverse decision under the Plan's external review procedures or in a court of law.

Instructions for filing an external review of a specialty prescription drug benefit claim will be provided to you in the notice of denial on appeal, if your claim is eligible for external review.

#### **Contact Information**

For questions about the Plan's coverage of specialty medications, please contact VIVIO, the claims administrator for the specialty prescription drug benefits provided under the Plan, by phone at 800-470-4034 or via email at <a href="mailto:concierge@myvivio.com">concierge@myvivio.com</a>. You may also log onto <a href="mailto:mymohawkbenefits.com">mymohawkbenefits.com</a> or contact the Benefits Service Center at 1-866-481-4922.

EXCEPT AS SPECIFICALLY MODIFIED ABOVE, THE TERMS OF THE PLAN REMAIN UNCHANGED AND IN FULL FORCE AND EFFECT. THIS SMM SHOULD BE KEPT WITH THE SPDS PREVIOUSLY FURNISHED TO YOU. IF THERE IS A CONFLICT BETWEEN THE CONTENTS OF THIS SMM AND THE CONTENTS OF THE INSURANCE CONTRACTS OR CERTIFICATES APPLICABLE TO THE PLAN, THE INSURANCE CONTRACTS AND CERTIFICATES FOR THE PLAN WILL CONTROL. COPIES OF THE PLAN DOCUMENTS, INCLUDING ITS UNDERLYING INSURANCE CONTRACTS AND CERTIFICATES, MAY BE REQUESTED IN WRITING FROM THE BENEFITS SERVICE CENTER.