

Attachment C

Resulting NCAM Grading Manual (Combining A + B)

July 6, 2022

NCAM Claim Grading Manual for the Purdue P.I.
Trust and MNK P.I. Trust

PREAMBLE

This manual is to be used for both the Purdue and MNK P.I. Trusts. The status of each trust is summarized below.

The Purdue P.I. Trust is scheduled to be established after appeals are exhausted and pursuant to the *Twelfth Amended Joint Chapter 11 Plan of Reorganization of Purdue Pharma L.P. and Its Affiliated Debtors*, dated September 2, 2021 (the “Purdue Plan”), and an Order confirming the Purdue P.I. Plan entered by the United States Bankruptcy Court for the Southern District of New York in the jointly administered chapter 11 cases (the “Bankruptcy Case”) of Purdue Pharma L.P. and its affiliate debtors (together with Purdue Pharma L.P., the “Debtors”), for purposes of processing and resolving approximately up to 140,000 filed personal injury claims against one or more of the Debtors. Purdue Pharma filed for Bankruptcy protection in 2019 from thousands of lawsuits over OxyContin and other opioid products. Edgar C. Gentle, III, has been appointed as the Trustee and Claims Administrator of the Purdue P.I. Trust, and the Effective Date of the Purdue P.I. Plan is uncertain. The Purdue P.I. website can be located at purduepitrust.com.

The MNK P.I. Trust has been established pursuant to the *Fourth Amended Joint Chapter 11 Plan of Reorganization of Mallinckrodt PLC and Its Debtor Affiliates*, filed on February 18, 2022 (the “MNK Plan”), and an Order confirming the MNK P.I. Plan entered by the United States Bankruptcy Court for the District of Delaware in the jointly administered chapter 11 cases (the “Bankruptcy Case”) of Mallinckrodt PLC and its affiliate debtors (together with Mallinckrodt PLC, the “Debtors”), for purposes of processing and resolving approximately an unknown number of personal injury claims that are not filed channeled to the MNK P.I. Trust. Edgar C. Gentle, III, has been appointed as the Trustee and Claims Administrator of the MNK P.I. Trust, and the Effective Date is June 16, 2022. Claims are anticipated to be admitted on approximately August 1, 2022. The MNK P.I. website can be located at mnkpitrust.com.

There are two types of personal injury claims under both Plans: NAS P.I. Claims and Non-NAS P.I. Claims.¹ This manual is related to NAS P.I. Claims. A NAS P.I. Claim is a claim for alleged opioid-related personal injury to a NAS Child or similar opioid-related cause of action. Neonatal Abstinence Syndrome (“NAS”) is a condition that newborns may experience as a result of prenatal exposure to certain substances, most often narcotics such as opioids. A successful NAS P.I. Claim for either the Purdue or MNK P.I. Trusts requires a diagnosis by a licensed medical provider of a medical, physical, cognitive, or emotional condition resulting from the NAS Child’s intrauterine exposure to opioids or opioid replacement or treatment medication, including but not limited to the condition known as neonatal abstinence syndrome (“NAS”).

To facilitate the grading of NAS Claims, the NAS Claimant’s Counsel created the Neonatal Claims Administration Manual (“NCAM”) on January 13, 2022, which includes relevant ICD codes and various other medical diagnosis to use when looking through medical records. A NAS Claimant qualifies in either the Purdue P.I. or MNK P.I. Trust. James R. Hocker, MD, was engaged by the Trustee and Claims Administrator to review the NCAM, and his expert opinion dated June 2, 2022 was independently obtained to assess the scientific reasonableness of the NCAM’s claims admission criteria. This document is the result of combining the NCAM with Dr.

¹ The MNK P.I. Plan also provides for Future P.I. Claims.

July 6, 2022

Hocker's Expert Opinion to be used as a Grading Manual for NAS claims in both the Purdue and MNK P.I. Trusts.

I. Medical Records Review Protocol

For the claim to qualify under the TDP, you must find

- A diagnosis by a licensed medical provider of a medical, physical, cognitive, or emotional condition resulting from the NAS Child's intrauterine exposure to opioids or opioid replacement or treatment medication, including but not limited to the condition known as neonatal abstinence syndrome ("NAS").

*****This is established by:**

- 1) evidence of an opioid-related exposure in utero and**
- 2) an opioid-related injury.**

Each child must show at least one form of evidence with documentation necessary for the proof of claim in the TDP:

- 1) Actual Diagnosis of NAS/IUDE Plus In Utero Opioid Exposure and/or NOWS**
Diagnosis of neonatal abstinence syndrome (NAS) or In Utero Drug Exposure (IUDE) for opioid exposure during pregnancy or neonatal opioid withdrawal syndrome (NOWS) or NAS/NOWS/IUDE ICD codes which are listed below that imply opioid exposure (if this isn't in the record, then continue to the next issue); OR
- 2) Evidence of Post-Birth Condition Related to Opioid Exposure In Utero**
Diagnosis of child with a medical, physical, cognitive, or emotional condition resulting from the child's exposure to opioids or opioid replacement or treatment medication during pregnancy, including but not limited to the condition known as NAS—the list of conditions is attached (if this isn't in the record, then continue to the next issue); OR
- 3) Evidence Implying Opioid In Utero Exposure-Related Diagnosis**
Other medical records evidencing that the child had an NAS diagnosis related to in utero opioid exposure, including post-natal treatment for symptoms caused by opioid exposure, symptoms of post-natal withdrawal from opioids, medical scoring for NAS or NOWS which is positive or indicates fetal opioid exposure (i.e. a score above zero), a positive toxicology screen of the birth mother or infant for opioids or opioid-weaning drugs, or a maternal diagnosis of opioid use disorder (OUD) by the birth mother.

1) Newborn ICD-9/ICD-10 codes [Establishes opioid exposure and injury]

There is agreement that the following ICD codes establish both exposure and injury, and are therefore sufficient for qualification:

- (i) NAS Neonatal Abstinence Syndrome/Opioid Withdrawal

779.5 (ICD-9 in utero drug exposure abstinence symptoms or syndromes neonatal; dependence—complicating pregnancy, childbirth, or puerperium affecting fetus or newborn)

P96.1 (ICD-10 neonatal withdrawal symptoms from maternal use of drugs of addiction)

F11.23 (ICD-10 opioid dependence with withdrawal)

(ii) In Utero Drug Exposure

760.72 (ICD-9 narcotics affecting fetus or newborn via placenta or breast milk)

760.79 (ICD-9 other noxious influences affecting fetus or newborn via placenta or breast milk)

P04.49 (ICD-10 infants affected by maternal use of drugs of addiction; newborn affected by maternal narcotic use)

P04.8 (ICD-10 newborn (suspected to be) affected by other maternal noxious substances)

P04.14 (ICD-10 newborn affected by maternal use of opiates, including Buprenorphine, Codeine, Fentanyl, Heroin, Methadone, Morphine, Meperidine, and Pentazocine)

P04.4 (ICD-10 newborn affected by maternal use of drugs of addiction)

P04.6 (ICD-10 newborn suspected to be affected by other maternal noxious substances)

P04.9 (ICD-10 newborn affected by maternal noxious substance, unspecified)

648.3 (ICD-9 drug dependence—complicating pregnancy, childbirth, or puerperium)

R78.1 (ICD-10 finding of opiate drug in blood)

2) Search terms associated with opioid exposures, such as morphine, narcotic, opiate, opioid, maternal noxious substance exposure, and others, review in within the context of use to indicate that the infant was exposed to these drugs in utero/during pregnancy [**Establishes opioid exposure**]

There is a table of additional opioids and MAT in Appendix A.

3) Diagnosis (ICD code or narrative) of child with a listed post-natal injury, including a medical, physical, cognitive, or emotional condition. [**Establishes injury**]

For a comprehensive list of approved injuries, see spreadsheet of ICD-9 and -10 codes in the attached materials.

4) Hospital discharge summaries with instructions for care of the infant exposed to opioids (NAS/NOWS), as well as any injuries/symptoms the infant may have. In general, the medical records may refer to maternal use of or infant withdrawal from opioids or opiates, so review should begin with those search terms. [**Establishes opioid exposure and injury**]

NAS/NOWS may be described as

- Newborn affected by maternal use of opiates
- Newborn affected by maternal use of drug of addiction
- Exposure to noxious substance affecting newborn, placenta, or breast milk

5) Newborn's toxicology reports that indicate presence of opioids/opiates before such time as any opioids were used therapeutically. Urine, meconium, placenta, hair (within 48 hours of birth), and/or other samples (within 48 hours of birth) may be tested as well. [**Establishes opioid exposure**]

6) NAS scoring also note whether the child was breastfed or not **[Establishes injury and exposure]**

Use of a published standardized scoring withdrawal assessment tool, including Finnegan Neonatal Abstinence Scoring System Tool, Lipsitz Neonatal Drug Withdrawal Scoring System, Neonatal Narcotic Withdrawal Index, Neonatal Withdrawal Inventory, MOTHER NAS Scale, and Finnegan Neonatal Abstinence Syndrome Scoring Tool-Short Form which results in the use of non-pharmacologic or pharmacologic treatment.

7) Any drugs administered to the baby during birth to treat withdrawal symptoms, including morphine, methadone, klonopin, phenobarbital, and others. This does not include those treated after therapeutic exposure to opioids used for pain or sedation. **[Establishes opioid exposure and injury]**

8) Post-natal hospital care: Use of any non-pharmacologic measure to treat symptoms of opioid withdrawal in a newborn as documented in the medical record. **[Establishes injury]**

Non-pharmacologic measures include but are not limited to

- modifying environmental stimulation after birth—
 - (i) Reduction of negative stimulation gentle handling, low-light/quiet environment, infant containment/swaddling, vibrating beds, positioning and non-oscillating waterbed
 - (ii) Promotion of positive experiences—non-nutritive sucking, aromatherapy, music therapy, massage, and acupuncture/acupressure
- modifying feeding practices any modification used to reduce withdrawal symptoms
- modifying support of the mother-infant dyad. This does not include those treated after therapeutic exposure to opioids used for pain or sedation.

9) In the absence of official diagnoses, there are ways that NAS or opioid exposure and injury linked can be diagnosed through implied birth characteristics. **[Establishes injury]**

This may include observations of any of the following **SIGNS** in newborn period (assuming other causes have been ruled out)

- any exposed newborn whose sleeping or feeding pattern has been adversely affected or who is deemed difficult to console as documented in the medical record
- difficulty swallowing or eating, loss of appetite (feeding difficulties)
- treated with a withdrawal treatment bundle
- prematurity (< 37 weeks gestation)
- low birth weight (< 2500 grams)
- length of hospital stay (5 days or more)
- skin excoriation requiring treatment (such as skin injuries, including scratches, excessive self-rubbing, dry skin, skin scaling/cracking, and sucking blisters)
- respiratory distress syndrome (tachypnea)
- diaper rash requiring treatment (such as prolonged antifungal medication)
- rigid or increased muscle tone (difficult to bend or straighten the arms)
- excessive irritability
- high-pitched crying

- reflux
- vomiting
- loose stools/diarrhea
- abnormal weight loss
- increased respiratory rate (above 60 breaths/minute)
- elevated temperature/fever (above 99.5 degrees F)
- sweating
- yawning
- tremors
- convulsions/seizures
- sneezing/runny nose
- elevated pain score
- feeding problems
- abnormal sleeping patterns

10) Birth mother opioid or MAT use. **[Establishes exposure]**

- The mother is known to be in an opioid addiction treatment program and was treated with methadone, suboxone, or subutex while pregnant.
- The mother admits to opioid use during pregnancy as documented in the medical record.
- The mother has pharmacy records or a bottle containing an opioid reflecting she picked up an opioid during pregnancy.
- A family member claims a mother was using an opioid during the pregnancy as documented in the medical record.
- The maternal urine drug screen is positive for an opioid.
- Any other maternally derived specimen (such as hair) is positive for an opioid if collected during pregnancy or within 48 hours of birth.

Maternal use of opioid replacement or treatment medication (also referred to as medication-assisted treatment MAT) may also be used.

A non-exhaustive alphabetical list of opioids and MAT drugs is contained in a table at the end of Sect. I if specific drug names are used, rather than general terms.

Codes related to birth mother opioid addiction and birth mother opioid use disorder (OUD) are included in Appendix B.

11) Diagnosis of opioid-related injury in the post-newborn period. **[Establishes injury]**

- growth delay
- learning difficulties
- disturbances of emotion
- problems interacting with peers

12) Presence of any of the following in infancy, childhood, or adolescence (assuming other causes have been ruled out). **[Establishes injury]**

- abnormal posture
- muscle contractures
- muscle spasms
- muscle weakness
- dietary counseling and surveillance
- contact with and exposure to viral hepatitis
- child in welfare custody
- child in foster care
- problem related to social environment

Appendix A

Prescription List

Opioids and opioid replacement or treatment medication (MAT) may include the following drugs (this is not an exhaustive list):

Acetaminophen and Codeine Phosphate	Morphine
Actiq	Morphine extended-release
Allay	Morphine immediate-release
Ambenyl	Morphine Sulfate oral
Anexsia	MS Contin
Bancap HC	MSIR (morphine sulfate immediate-release)
Buprenorphine and Naloxone Sublingual	Norco
Buprenorphine transdermal	Numorphan
Butrans	Opana
Capital and Codeine	Opana ER
Cassipa	Opiates, opioids
Codrix	Oral Transmucosal Fentanyl Citrate
Combunox	Oxycet
Demerol	Oxycodone
DHC Plus (dihydrocodeine)	Oxycodone and acetaminophen
Dihydrocodeine acetaminophen and caffeine	Oxycodone extended-release
Dilaudid	Oxycodone hydrochloride
Diskets	Oxycodone immediate-release

Dolophine	Oxycodone Oral
Duradyne DHC	OxyContin
Duragesic	OxyFast
Endocet	OxyIR
Exalgo	Oxymorphone hydrochloride
Fentanyl Transdermal System	Palladone
Fentora	Percocet
Fioricet with Codeine	Percodan
Hydrocodone	Percodan-Demi
Hydrocodone and acetaminophen	Roxanol
Hydrocodone extended-release	Roxicet
Hydromorphone extended-release	Roxicodone
Hydromorphone Hydrochloride	Ryzolt
Hydromorphone immediate-release	Suboxone
Hydromorphone injectable	Targiniq
Hydromorphone oral	Tramadol extended-release
Hysingla	Tramadol hydrochloride
Kadian	Tycolet
Levorphanol Tartrate	Tylenol with Codeine
Lorcet	Tylox
Lorcet-HD	Ultracet
Meperidine hydrochloride	Ultram
Methadone	Ultram
Methadone Hydrochloride	Vantrela
Methadone Hydrochloride Dispersible	Vicodin
Methadose	Xartemis
	Xartemis XR

Appendix B B. Birth mother opioid exposure codes

- F11.9 (ICD-10 opioid use, unspecified)
- F11.10 (ICD-10 opioid abuse, uncomplicated)
- F11.120 (ICD-10 opioid abuse with intoxication, uncomplicated)
- F11.121 (ICD-10 opioid abuse with intoxication, delirium)
- F11.122 (ICD-10 opioid abuse with intoxication, with perceptual disturbance)
- F11.129 (ICD-10 opioid abuse with intoxication, unspecified)
- F11.14 (ICD-10 opioid abuse with opioid-induced mood disorder)
- F11.150 (ICD-10 opioid abuse with opioid-induced psychotic disorder, with delusions)
- F11.151 (ICD-10 opioid abuse with opioid-induced psychotic disorder, with hallucinations)
- F11.159 (ICD-10 opioid abuse with opioid-induced psychotic disorder, unspecified)
- F11.181 (ICD-10 opioid abuse with opioid-induced sexual dysfunction)
- F11.182 (ICD-10 opioid abuse with opioid-induced sleep disorder)
- F11.188 (ICD-10 opioid abuse with other opioid-induced disorder)
- F11.19 (ICD-10 opioid abuse with unspecified opioid-induced disorder)

- F11.20 (ICD-10 opioid dependence, uncomplicated)
- F11.21 (ICD-10 opioid dependence, in remission)
- F11.220 (ICD-10 opioid dependence with intoxication, uncomplicated)
- F11.221 (ICD-10 opioid dependence with intoxication, delirium)
- F11.222 (ICD-10 opioid dependence with intoxication, with perceptual disturbance)
- F11.229 (ICD-10 opioid dependence with intoxication, unspecified)
- F11.23 (ICD-10 opioid dependence with withdrawal)
- F11.24 (ICD-10 opioid dependence with opioid-induced mood disorder)
- F11.250 (ICD-10 opioid dependence with opioid-induced psychotic disorder, with delusions)
- F11.251 (ICD-10 opioid dependence with opioid-induced psychotic disorder, with hallucinations)
- F11.259 (ICD-10 opioid dependence with opioid-induced psychotic disorder, unspecified)
- F11.281 (ICD-10 opioid dependence with opioid-induced sexual dysfunction)
- F11.282 (ICD-10 opioid dependence with opioid-induced sleep disorder)
- F11.288 (ICD-10 opioid dependence with other opioid-induced disorder)
- F11.29 (ICD-10 opioid dependence with unspecified opioid-induced disorder)
- F11.90 (ICD-10 opioid use, unspecified, uncomplicated)
- F11.920 (ICD-10 opioid use, unspecified with intoxication, uncomplicated)
- F11.922 (ICD-10 opioid use, unspecified with intoxication, with perceptual disturbance)
- F11.929 (ICD-10 opioid use, unspecified with intoxication, unspecified)
- F11.93 (ICD-10 opioid use, unspecified, with withdrawal)
- F11.94 (ICD-10 opioid use, unspecified, with opioid-induced mood disorder)
- F11.950 (ICD-10 opioid use, unspecified with opioid-induced psychotic disorder, with delusions)
- F11.951 (ICD-10 opioid use, unspecified with opioid-induced psychotic disorder, with hallucinations)
- F11.959 (ICD-10 opioid use, unspecified with opioid-induced psychotic disorder, unspecified)
- F11.981 (ICD-10 opioid use, unspecified with opioid-induced sexual dysfunction)
- F11.982 (ICD-10 opioid use, unspecified with opioid-induced sleep disorder)
- F11.988 (ICD-10 opioid use, unspecified with other opioid-induced disorder)
- F11.99 (ICD-10 opioid use, unspecified, with unspecified opioid-induced disorder)
- T40.2X (ICD-10 and the following subcategories for poisoning by opioids)
- T40.2X1A (ICD-10 poisoning by other opioids, accidental (unintentional), initial encounter)
- T40.2X1D (ICD-10 poisoning by other opioids, accidental (unintentional), subsequent encounter)
- T40.2X2A (ICD-10 poisoning by other opioids, intentional self-harm, initial encounter)
- T40.2X2D (ICD-10 poisoning by other opioids, intentional self-harm, subsequent encounter)
- T40.2X3A (ICD-10 poisoning by other opioids, assault, initial encounter)
- T40.2X3D (ICD-10 poisoning by other opioids, assault, subsequent encounter)
- T40.2X4A (ICD-10 poisoning by other opioids, undetermined, initial encounter)
- T40.2X4D (ICD-10 poisoning by other opioids, undetermined, subsequent encounter)

T40.3X (ICD-10 poisoning by methadone and the following subcategories)
 T40.3X1A (ICD-10 poisoning by methadone, accidental (unintentional), initial encounter)
 T40.3X1D (ICD-10 poisoning by methadone, accidental (unintentional), subsequent encounter)
 T40.3X2A (ICD-10 poisoning by methadone, intentional self-harm, initial encounter)
 T40.3X2D (ICD-10 poisoning by methadone, intentional self-harm, subsequent encounter)
 T40.3X3A (ICD-10 poisoning by methadone, assault, initial encounter)
 T40.3X3D (ICD-10 poisoning by methadone, assault, subsequent encounter)
 T40.3X4A (ICD-10 poisoning by methadone, undetermined, initial encounter)
 T40.3X4D (ICD-10 poisoning by methadone, undetermined, subsequent encounter)
 T40.0X5 (ICD-10 adverse effects of opioids and subcategories below)
 T40.2X5A (ICD-10 adverse effect of other opioids, initial encounter)
 T40.2X5D (ICD-10 adverse effect of other opioids, subsequent encounter)
 T40.3X (ICD-10 adverse effect of methadone and subcategories below)
 T40.3X5A (ICD-10 adverse effect of methadone, initial encounter)
 T40.3X5D (ICD-10 adverse effect of methadone, subsequent encounter)
 Z79.891 (ICD-10 long term use of opiate analgesic, methadone for pain management)

292.0 (ICD-9 opioid withdrawal, comorbid moderate or severe opioid use disorder)
 292.89 (ICD-9 opioid intoxication without perceptual disturbances)
 292.9 (ICD-9 unspecified opioid-related disorder)
 304.00 (ICD-9 opioid dependence-unspecified)
 304.01 (ICD-9 opioid dependence-continuous)
 304.02 (ICD-9 opioid dependence-episodic)
 304.03 (ICD-9 opioid dependence-in remission)
 304.7 (ICD-9 dependence—combination morphine or opioid type drug with any other drug)
 304.70 (ICD-9 opioid and other drug dependence-unspecified)
 304.71 (ICD-9 opioid and other drug dependence-continuous)
 304.72 (ICD-9 opioid and other drug dependence-in remission)
 304.8 (ICD-9 polysubstance dependence)
 305.50 (ICD-9 opioid abuse-unspecified)
 305.51 (ICD-9 opioid abuse-continuous)
 305.52 (ICD-9 opioid abuse-episodic)
 305.53 (ICD-9 opioid abuse-in remission)
 965.00 (ICD-9 poisoning by opium (alkaloids), unspecified)
 965.02 (ICD-9 poisoning by methadone)
 965.99 (ICD-9 opium poisoning)
 965.09 (ICD-9 poisoning by other opiates and related narcotics)
 970.1 (ICD-9 poisoning by opiate antagonists)
 E850.1 (ICD-9 accidental poisoning by methadone)
 E850.2 (ICD-9 accidental poisoning by other opiates and related narcotics)
 E935.1 (ICD-9 methadone causing adverse effects in therapeutic use)

July 6, 2022

E935.2 (ICD-9 other opiates and related narcotics causing adverse effects in therapeutic use)

E940.1 (ICD-9 adverse effects of opiate antagonists)

E980.0 (ICD-9 undetermined cause poisoning by opiates)