

NAS CLAIM GRADING MATERIALS

Attachment C provides the NCAM Grading Manual for NAS Claims, and may be used in preparing the Claim Form and related materials for a NAS Claimant seeking admission to the Settlement Program.

This document is the result of the following process.

NAS Counsel prepared the proposed NAS Claims Admission Manual (“NCAM”) for this purpose on January 13, 2022, contained in Attachment A. The Trustee then had the NCAM reviewed by a Neonatologist, who provided his Professional Opinion in Attachment B.

Attachment C is the resulting NCAM Grading Manual from combining A and B.

Finally, the Neonatologist Expert, in Attachment D, provides his imprimatur, approving the NCAM Grading Manual in Attachment C.

Attachment A

The Original NCAM



NCAM

NAS Claims Admission Manual

1-13-22 DRAFT

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 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.

The following review is to be conducted in order of priority. Find and highlight the relevant information in the medical documentation in order of this priority within the first 45-minutes of review:

- 1) 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. 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.** **[Establishes exposure and injury]**

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NAS/NOWS may be described as

- Newborn affected by maternal use of opiates
- Newborn affected by maternal use of drug of addiction
- Drug withdrawal syndrome in newborn
- Maternal substance abuse affecting newborn
- Exposure to noxious substance affecting newborn, placenta, or breastmilk

Codes related to birth mother opioid addiction and birth mother opioid use disorder (OUD) are included at the end of Sect. I.

If the above are found, confirm the drug of exposure is an opioid or opioid replacement such as:

- Oxycodone
- Hydrocodone
- Oxycontin
- Percocet
- Fentanyl
- Tramadol
- Subutex
- Suboxone
- Methadone

There is also a table of additional opioids and MAT at the end of Sect. I.

2) Newborn ICD-9/ICD-10 codes [establishes opioid exposure and injury]

****Seeking approval of the following ICD codes from the Claim Administrator as sufficient for qualification:****

P96.1 (ICD-10 neonatal withdrawal symptoms)

P96.2 (ICD-10 withdrawal symptoms from therapeutic use of drugs in newborn)

F11.20 (ICD-10 maternal dependence on opioids)

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

P04.1 (ICD-10 newborn affected by other maternal medication)

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

P04.14 (ICD-10 newborn affected by maternal use of opiates)

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

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

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

Q86.8 (ICD-10 other congenital malformation syndromes due to known exogenous causes)

Z92.29 (ICD-10 personal history of other drug therapy)

Z87.898 (ICD-10 personal history of other specified conditions)

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

760.72 (ICD-9 narcotics affecting fetus or newborn via placenta or breast milk—noxious influences affecting fetus or newborn via placenta or breast milk, narcotics)

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760.79 (ICD-9 other noxious influences affecting fetus or newborn via placenta or breast milk)
648.3 (ICD-9 drug dependence—complicating pregnancy, childbirth, or puerperium)
648.32 (ICD-9 drug dependence of mother, delivered, with mention of postpartum complication)
V87.49 (ICD-9 personal history of other drug therapy)
V13.89 (ICD-9 personal history of other specified diseases)

- 3) Toxicology reports—either the child’s or mother’s—that indicate presence of opioids/opiates (urine, meconium, placenta, and/or hair may be tested as well) [**Establishes opioid exposure**]
- 4) NAS scoring—there are different methods of scoring, in addition to Finnegan’s—also note whether the child was breastfed or not [**Establishes opioid exposure and injury**]
- 5) Any drugs administered to the baby during birth to treat withdrawal symptoms, including morphine, methadone, klonopin, phenobarbital, and others [**Establishes injury, if withdrawal symptom drug is an opioid, then this establishes opioid exposure**]
- 6) 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**]
- 7) 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 (but are not limited to) observations of any of the following infant conditions after birth:

- length of hospital stay (5 days or more)
- respiratory distress syndrome (including tachypnea and aspiration)
- skin excoriation (skin injuries, including scratches, excessive self-rubbing, dry skin, skin scaling/cracking, and sucking blisters)
- diaper rash requiring prolonged antifungal medication
- rigid or increased muscle tone (difficult to bend or straighten the arms)
- gastroesophageal reflux (GERD)/acid reflux not responsive to daily medications
- head lag
- infant medication used: morphine, methadone, phenobarbital, tincture of opium
- hyperactive Moro (arms staying up, jitteriness of hands)
- irritability
- high-pitched crying
- difficulty sleeping
 - difficulty swallowing or eating (feeding difficulties)
 - loss of appetite
- weight loss
 - excessive sucking

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- vomiting
 - diarrhea
 - excessive runny nose
 - fever
 - heavy sweating
 - tremors
 - convulsions and/or seizures
 - prematurity
 - low birth weight
 - blotchy skin
 - sneezing/runny nose
 - signs of pain
 - childhood chronic asthma with multiple exacerbations not responsive to daily medication
- 8) Diagnosis of child with a post-natal (long-term) injury, including a medical, physical, cognitive, or emotional condition. **[Establishes injury]**

*For an comprehensive list of approved injuries, see spreadsheet of ICD-9 and -10 codes in the Sect. I materials. ****Seeking approval from the Claim Administrator of the ICD codes in the spreadsheet attached as establishing post-natal injury.*****

Once you have spent 45 minutes locating and highlighting the relevant information, upload the record with the highlights into Law Ruler and to the Claim Administrator ftp site folder. Fill in the data in all columns in the medical review spreadsheet for claimant.

Appendix

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

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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

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)

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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)

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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)

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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)
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)

II. Identifying Neonatal Abstinence Syndrome (NAS), Neonatal Opioid Withdrawal Syndrome (NOWS), & In Utero Drug Exposure (IUDE) Through International Classification of Diseases (ICD) Codes

In 2014, it was estimated that a baby was born suffering from in utero opioid exposure withdrawal every 15 minutes in the United States (National Institute on Drug Abuse, NIDA). The rate of opioid exposure withdrawal increased from 1.5 babies per 1,000 hospital births in 2004 to 3.4 in 2009 (NIDA). From 2010 through 2017, it is estimated that babies born with Neonatal Abstinence Syndrome (NAS) increased from 4.0 per 1,000 birth hospitalizations to 7.3 (Hirai 2021). At that same time, the estimated maternal opioid-related diagnoses (MOD) in the United States increased from 3.5 per 1,000 deliveries to 8.2 (Hirai 2021). This directly correlates with the increased usage of opioids by the general public, as well as pregnant women, as those rates continued to rise.

NAS and the public's opioid use are highly correlated. The high incidence of NAS grew over sevenfold from 2010-2020 as the prevalence of opioid use in the US increased (Maalouf 2019). Opioid-related drug exposure in NAS was so prevalent that throughout the NAS epidemic, NAS as a condition has often been used to generally refer to opioids as the drug of exposure, rather than a general term covering all drugs of substance use (Maalouf 2019). Thus, NAS is often synonymous with opioid exposure. This is reflected in research validating NAS ICD codes from opioid exposure. Maalouf, et al. validated NAS ICD codes as specific to opioid withdrawal using opioid-specific withdrawal symptoms and treatment. Through this validation, NAS under ICD-9 code 779.5 was opioid-related in 91% of the cases. NAS under ICD-10 code P96.1 was opioid-related in 98.2% cases (Maalouf 2019).

Much of the research on opioid-related NAS focus on a few main ICD-9 and -10 codes, particularly 779.5 and P96.1 (Harai 2021). However, there is no one standard ICD-9 or -10 code that has been identified as uniformly and/or universally applied billing code, which has frustrated epidemiologists studying the NAS epidemic (see attached literature regarding academic research methods of identifying children exposed to opioids, particularly the presentation by the Council of State and Territorial Epidemiologists, CSTE—*NAS Standardized Surveillance Case Definition Position Statement*). Billing code practices vary by healthcare system and/or region of the country. Moreover, because the ICD code is a method of billing insurance and not strictly a medical diagnoses, the type of and/or insurance company covering the child may dictate what codes are used for reimbursement.

Adding to this insurance issue is that the coding systems have changed (though not at the same time or uniformly) from ICD-9 to ICD-10 during the period of time affecting this class of children. Moreover, the rates of opioid-related NAS cases do vary, depending on the sources of data and methods of review, further demonstrating that there is not one source of information to identify opioid-exposed babies (for example, compare Harai, et al. NAS rates to NIDA for the time period of 2010-2014). In fact, over fifteen years into this devastating epidemic, states do not have a uniform comprehensive surveillance system for NAS, Neonatal Opioid Withdrawal Syndrome (NOWS), and/or In Utero Drug Exposure (IUDE) (Binkin 2019, CSTE 2019).

It is likely that opioid-related births may be undercounted for a variety of reasons. “No studies have validated opioid-related diagnoses (MOD) from hospital discharge records, either in

pregnancy or more generally, but some evidence indicates substantial under-ascertainment” (Hirai 2021). Anonymous surveys from the National Survey of Drug Use and Health find higher rates of self-reported past-month opioid *misuse* in pregnant women (1.4%) than MOD coded births (0.8%) (Hirai 2021). It is well-known throughout the behavioral health professional and academic community that self-reported *misuse* is often underreported as well, so this data raises issues that MOD birth rates may be significantly under-reported if misuse.

Recognizing the lack of uniformity in the NAS/NOWS/IUDE some researchers have cast a wide net in hopes of comprehensively identifying NAS cases (Arter 2021, Krause 2021, Goyal 2020, Binkin 2019, CSTE 2019). Those researchers have found that limiting ICD codes in reporting results in an undercounting of NAS/NOWS/IUDE cases (Krause 2021, Goyal 2020). Because of the high predictive value of billing codes with opioid-related exposures in the academic literature, as well as the dramatically high rates of babies born with opioid-specific withdrawals, it is reasonable and defensible that we cast a wide net of codes for the TDP to cover children whose hospitals may have used alternative billing codes for a variety of reasons, including a lack of knowledge about opioid-related NAS or restrictive insurance billing practices. We have identified the following list of codes to evidence for the TDP that a child was born with NAS, NOWS, and/or IUDE, which may be due to in utero exposure to opioids or opioid replacement or treatment therapy (medication assisted treatment, MAT).

Proposed Newborn Codes

- P96.1 (ICD-10 neonatal withdrawal symptoms)
 - P96.2 (ICD-10 withdrawal symptoms from therapeutic use of drugs in newborn)
 - F11.20 (ICD-10 maternal dependence on opioids)
 - F11.23 (ICD-10 opioid dependence with withdrawal)
 - P04.1 (ICD-10 newborn affected by other maternal medication)
 - P04.4 (ICD-10 newborn affected by maternal use of drugs of addiction)
 - P04.14 (ICD-10 newborn affected by maternal use of opiates)
 - P04.49 (ICD-10 infants affected by maternal use of drugs of addiction)
 - P04.8 (ICD-10 newborn (suspected to be) affected by other maternal noxious substances)
 - P04.9 (ICD-10 newborn affected by maternal noxious substance, unspecified)
 - Q86.8 (ICD-10 other congenital malformation syndromes due to known exogenous causes)
 - Z92.29 (ICD-10 personal history of other drug therapy)
 - Z87.898 (ICD-10 personal history of other specified conditions)
-
- 779.5 (ICD-9 in utero drug exposure—abstinence symptoms or syndromes—neonatal; dependence—complicating pregnancy, childbirth, or puerperium—affecting fetus or newborn)
 - 760.72 (ICD-9 narcotics affecting fetus or newborn via placenta or breast milk—noxious influences affecting fetus or newborn via placenta or breast milk, narcotics)
 - 760.79 (ICD-9 other noxious influences affecting fetus or newborn via placenta or breast milk)
 - 648.3 (ICD-9 drug dependence—complicating pregnancy, childbirth, or puerperium)
 - 648.32 (ICD-9 drug dependence of mother, delivered, with mention of postpartum complication)
 - V87.49 (ICD-9 personal history of other drug therapy)
 - V13.89 (ICD-9 personal history of other specified diseases)

References

The below articles are included in the Sect. 2 materials.

Arter S., et al. Diagnoses During First Three Years of Life for Children with Prenatal Opioid Exposure and Neonatal Abstinence Syndrome Using a Large Maternal Infant Data Hub, *Journal of Pediatric Nursing*. 61:34-39 (2021).

Binkin N. Neonatal Abstinence Syndrome (NAS) Environmental Scan and Key Informant Interview Analysis Report, *Council of State and Territorial Epidemiologists* (2019). https://cdn.ymaws.com/www.cste.org/resource/resmgr/pdfs/pdfs2/NAS_Environmental_Scan_Report.pdf

Council of State and Territorial Epidemiologists (CSTE). *Neonatal Abstinence Syndrome (NAS) Standardized Surveillance Case Definition Position Statement*. (2019). <https://kansaspqc.org/wp-content/uploads/2019/06/Slides-Kasehagen-Jackson-Coding-NAS.pdf>

Goyal S., et al. Identification of Substance-Exposed Newborns and Neonatal Abstinence Syndrome Using ICD-10 CM—15 Hospitals, Massachusetts, 2017, *Morbidity and Mortality Weekly Report* (US Department of Health and Human Services/Centers for Disease Control and Prevention). 69(29):951-955 (2020).

Harai A., et al. Neonatal Abstinence Syndrome and Maternal Opioid-Related Diagnoses in the U.S. 2010-2017, *Journal of the American Medical Association*. 325(2):146-155 (2021).

Krause K., et al. Assessment of Neonatal Abstinence Syndrome Surveillance—Pennsylvania, 2019, *Morbidity and Mortality Weekly Report* (US Department of Health and Human Services/Centers for Disease Control and Prevention). 70(2):40-45 (2021).

Maalouf F, et al. Positive Predictive Value of Administrative Data for Administrative Data for Neonatal Abstinence Syndrome, *Pediatrics*. 143(1):e20174183 (2019).

National Institute on Drug Abuse (NIDA) 2019. <https://archives.drugabuse.gov/trends-statistics/dramatic-increases-in-maternal-opioid-use-neonatal-abstinence-syndrome>

III. Purdue Discovery Documents for NAS Claims Administration Manual

Under the TDP, NAS claimants who were not assessed post-natal NAS scores and/or did not exhibit post-natal NAS withdrawal due to withdrawal in the womb may file claims and are entitled to compensation. There are a variety of reasons why a NAS child may not have had a NAS score, including the time period in which the child exposed to opioids in the womb (for example, older NAS claimants may have been born in healthcare systems which had not implemented uniform NAS testing at the beginning of the NAS opioid epidemic). Other NAS children who were exposed to opioids in the womb but were not born while still the birth mother was taking opioids may still have NAS health damages, despite not suffering NAS post-natal withdrawal.

Much of the Purdue internal scientific knowledge on the impacts of opioids on fetuses and women have not been published or provided to the public. Under information and belief, some of these studies were not provided to the FDA. This includes animal studies with findings on physical and neurobehavioral impacts, as well as human drug studies with findings that women retain higher levels of opioids in their plasma than men, *even accounting for body weight*.

Although many babies are diagnosed with NAS at birth, or in the days following birth due to the symptoms and conditions associated with opioid dependency and withdrawal, other babies are discharged with malformations and disorders associated with fetal opioid exposure. Many others—including those diagnosed with NAS and those not—may manifest latent injuries while infants, toddlers, or older. These injuries may have long-term or lifelong medical care implications. The impacts to NAS children are much more complex in scope than the withdrawal symptoms at birth that were sometimes mentioned by Purdue in its prescribing documents. It includes injuries such as skull malformations and other skeletal malformations, feeding complications, heart and other organ defects, respiratory dysfunction, and behavioral and long-term cognitive issues. All of these medical conditions represent some of the many medical conditions that, unfortunately, are commonly associated with fetal opioid exposure, regardless of whether NAS withdrawal symptoms were observed or adequately documented at birth.

The documents in the Sect. 3 materials are not currently available to the public, including the NAS Claimants and those caregivers of the NAS Claimants. However, they are essential for NAS Claimants to understand the nature of their claims and their rights under the TDP and settlement. They were also extensively reviewed in drafting the NCAM, including the list of injuries that NAS Claimants may use to file claims under the TDP. Additional information can be found in file Opioid- CCDS- timelines wk 4-13-21 2.xlsx in the Sect. 3 materials.

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Document	Reason for Public Disclosure	Identification Information
Expert Report of Dr. Anand	Expert findings related to birth defects and opioid exposure.	Plaintiffs' Expert Report Prepared for NASAHC
Expert Report of Dr. Howard	Expert findings related to birth defects and opioid exposure.	Plaintiffs' Expert Report Prepared for NASAHC
NDSE-555-GLP A Pre- and Postnatal (Segment III) Study in Rats with Topically Applied Buprenorphine Patches and Subcutaneously Administered Buprenorphine HCl	Testing of Buprenorphine; study of 3 generations of rats—F0 maternal dosed, F1 in utero exposed, and F3 post-in utero non-exposed generation—findings of F1 increased pup deaths at birth, increased pup deaths during lactation, lower birth rates; F1 behavioral issues, including reduced eye opening, overall response, auditory, processing, and memory; F1 collapsed lung findings	PAK002329104- PAK002329635
Kaiko, R. F ., Benziger, D.P ., Fitzmartin, R.D., Burke, B.E., Reder, R.F., and Goldenheim, P.D. Pharmacokinetic/pharmacodynamic relationships of controlled-release oxycodone. Clin. Pharm. Ther. 59: 52-61 (1996).	Oxycontin HCl study in humans; higher plasma concentrations were found in women	PDD8013105266- PDD8013105276
OXY-N-003 Oxycodone Hydrochloride An Oral Fertility and Early Embryotic Development Study in Rats	Oxycontin HCl study in rats; male and female fertility studied; maternal behavioral changes (excessive licking, chewing, and self-harm); weight gains in females greater than controls; lower food consumption for pregnant females; no	PDD8013253884- PDD8013254903

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	observed effect level (NOEL) established for F1 early embryotic development	
OXY-N-004 A Prenatal and Postnatal Development Study with Oxycodone in Rats	Oxycontin HCl study in rats; toxic reproductivity studied; F0 dosed day 6 to lactation day 21 or 22; behavioral observations of F1 generation exposed in utero, including postweaning and eye opening, reflexology, and sensory development; no observed effect level (NOEL) established for F1 early embryotic development	POK000386923- POK000389368
Mallinckrodt Dossier for Oxycontin (Germany)	p. 33 (PDD1701384857) Section 4.6 Pregnancy and Lactation "The product must not be used during pregnancy and lactation."	PDD1701384825- PDD1701385208
Periodic Safety Update Report 2006-2007	Summary of significant findings, includes studies conducted for updates	PDD8013418569- PDD8013418582
Periodic Safety Update Report 2007-2008	Summary of significant findings, includes studies conducted for updates	PPLPC020000181909- PPLPC020000181917
Periodic Safety Update Report 2007-2008 (additional annual update)	Summary of significant findings, includes studies conducted for updates	PDD8013421495- PDD8013423148
Periodic Safety Update Report 2008-2009	Summary of significant findings, includes studies conducted for updates	POK000014647- POK000015147
Periodic Safety Update Report 2009-2010	Summary of significant findings, includes studies conducted for updates	POK000028449- POK000030681
2010-2011 Oxycodone Periodic Safety Update Report	Summary of significant findings and studies conducted for updates, also contains internal Purdue literature review of the Broussard study which found a linkage between	PMT003878737- PMT003883905

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	birth defects and opioid use during pregnancy.	
2016 Periodic Safety Update Report for Oxycodone	Summary of significant findings, includes studies conducted for updates	PPLPC056000664380-PPLPC056000665191
1998 Investigator's Brochure - Hydrocodone CR tablets	Notes potential teratogenic effects to animals from hydrocodone and excretion in breast milk. (see warnings at PKY183400824).	PKY183400781-PKY183400834
Adverse Event Reports Jan 1990 - Oct 2018	Summary of adverse events related to pregnancy, birth defects, neonatal withdrawal, and lactation.	PPLP004390587
Swedish SMPC Opidol Summary of Product Characteristics	Shows development of knowledge related to pregnancy, neonatal withdrawal, and lactation.	E513_00046100
Oxycontin Tablets Package Insert (7/1/1996)	Information for safe use, pregnancy, neonatal withdrawal, and lactation	PPLP004390587
Oxycontin Tablets Package Insert (2008)	Information for safe use, pregnancy, neonatal withdrawal, and lactation	PMT003878225
Oxycontin Highlights of Prescribing Information (4/2013)	Information for safe use, pregnancy, neonatal withdrawal, and lactation	E513_00045953
Oxycontin Highlights of Prescribing Information (8/4/2014)	Information for safe use, pregnancy, neonatal withdrawal, and lactation	E513_00046100
Oxycontin Highlights of Prescribing Information (8/2015)	Information for safe use, pregnancy, neonatal withdrawal, and lactation	E513_00045974
Oxycontin Highlights of Prescribing Information (12/2016)	Information for safe use, pregnancy, neonatal withdrawal, and lactation	Publicly Available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/022272s0341bl.pdf

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<p>Oxycontin Highlights of Prescribing Information (9/2018)</p>	<p>Information for safe use, pregnancy, neonatal withdrawal, and lactation</p>	<p>Publicly Available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/022272s040s0411bl.pdf</p>
<p>M. Broussard, "Maternal Treatment of with opioid analgesics and risk for birth defects" American Journal of Obstetrics & Gynecology, Volume 204, Issue 4 (April 2011)</p>	<p>Study on relationship between birth defects and opioid use by mothers during pregnancy. "Conclusion: Consistent with some previous investigations, our study shows an association between early pregnancy maternal opioid analgesic treatment and certain birth defects. This information should be considered by women and their physicians who are making treatment decisions during pregnancy."</p>	<p>Abstract Available at https://experts.unthsc.edu/en/publications/maternal-treatment-with-opioid-analgesics-and-risk-for-birth-defe</p>
<p>Doc 16 1994 Archival New Drug Application for Oxycodone Hydrochloride "Desk Copy"</p>	<p>Original 1994 prescribing language warnings for Oxycontin is found at PURCHI-000572404.</p>	<p>PURCHI-000572404- PURCHI-000572777</p>

**ATTACHMENTS ARE NOT PROVIDED
BUT INCLUDE THE FOLLOWING STUDIES AND MATERIALS:**

1. Expert Report of Dr. Anand
2. Expert Report of Dr. Howard
3. NDSE-555-GLP A Pre- and Postnatal (Segment III) Study in Rats with Topically Applied Buprenorphine Patches and Subcutaneously Administered Buprenorphine HCL
4. Kaiko, R.F., Benziger, D.P., Fitzmartin, R.D., Burke, B.E., Reder, R.F., and Goldenhiem, P.D. Pharmacokinetic/pharmacodynamic relationships of controlled-release oxycodone.
5. OXY-N-003 Oxycodone Hydrochloride an Oral Fertility and Early Embryotic Development Study in Rats
6. OXY-N-004 A Prenatal and Postnatal Development Study with Oxycodone in Rats
7. Mallinkrodt Dossier for Oxycontin
8. Periodic Safety Update Report 2006-2007
9. Periodic Safety Update Report 2007-2008
10. Periodic Safety Update Report 2007-2008 (additional annual update)
11. Periodic Safety Update Report 2008-2009
12. Periodic Safety Update Report 2009-2010
13. 2010-2011 Oxycodone Periodic Safety Update Report
14. 2016 Periodic Safety Update Report for Oxycodone
15. 1998 Investigator's Brochure - Hydrocodone CR tablets
16. Adverse Event Reports Jan 1990 - Oct 2018
17. Swedish SMPC Opidol Summary of Product Characteristics
18. Oxycontin Tablets Package Insert (7/1/1996)
19. Oxycontin Tablets Package Insert (2008)
20. Oxycontin Highlights of Prescribing Information (4/2013)
21. Oxycontin Highlights of Prescribing Information (8/4/2014)
22. Oxycontin Highlights of Prescribing Information (8/2015)
23. Oxycontin Highlights of Prescribing Information (12/2016)
24. Oxycontin Highlights of Prescribing Information (9/2018)
25. M. Broussard, "Maternal Treatment of with opioid analgesics and risk for birth defects" American Journal of Obstetrics & Gynecology, Volume 204, Issue 4 (April 2011)
26. Doc 16 1994 Archival New Drug Application for Oxycodone Hydrochloride "Desk Copy"
27. ICD 9 and 10 Codes
28. NAS Coding Articles

Attachment B

Dr. Hocker's Neonatologist Professional Opinion Re the NCAM

**Prepared at the Request of the Trustee of the Purdue Pharma Personal Injury Trust
Settlement (the "PI Trust")**

EXPERT OPINION OF JAMES R. HOCKER, MD

BEFORE ME, the undersigned authority personally came and appeared, James R. Hocker, MD, known to me and known to me to be the person so described who, after being duly sworn on oath, says that the following information is true and correct according to Affiant's best knowledge and belief:

A. INTRODUCTION

1. I am licensed to practice medicine in the State of North Dakota and have actively engaged in and practiced medicine for 31 years. My Curriculum Vitae is in Exhibit A.

2. As I understand it, I have been retained by the Trustee of the Purdue Pharma Personal Injury Trust Settlement (the "PI Trust"), to provide the PI Trust with an expert opinion on the present scientific reasonableness of the draft Neonatal Abstinence Syndrome ("NAS") Claimant personal injury admission criteria developed by Counsel for some of the NAS Claimants for review by the Trustee of the PI Trust (the "NCAM"). As I understand it, the NCAM provides a mechanism recommended by NAS Counsel to grade the claims of all potential Claimants fairly and equally, in finding whether or not there is opioid product causation for the Claimant, which I understand is established by both (1) evidence of the Claimant's opioid-related exposure in utero and (2) the Claimant's opioid-related injury. As I understand it, NAS Counsel believes that use of the NCAM to make that opioid product causation finding or the lack thereof, will facilitate a fair, uniform, objective and transparent claims grading process to be followed by the Trustee and Claims Administrator of the PI Trust. The NCAM, without the studies cataloged in Exhibit C, is in Exhibit B. Note that the science applicable to what injuries are opioid-related continues to evolve and expand. Therefore, this opinion, in deciding whether an injury is opioid-related, is a snapshot static present finding based on a dynamic evolving body of science. Therefore, an opinion that an injury is not substantiated as opioid-related is not a finding that opioid exposure

did not cause the injury, but only that it is not established in the scientific literature at this time. This leads to two recommendations for currently unsubstantiated injuries: (1) A Claimant only having unsubstantiated injuries may be encouraged to describe any other injuries, to determine if some are substantiated, and the presence of more than one unsubstantiated injury may, in the P.I. Trustee's discretion, be considered in deciding whether or not to admit the Claimant; and (2) this opinion may be modified periodically to reflect updates in the science of opioid injury causation.

3. The NCAM is comprised of a Medical Records Review Protocol, as well as International Classification of Diseases ("ICD") codes which Counsel for NAS Claimants believe are expected to appear in a potential Claimant's medical billing records if there has been opioid use by the mother or opioid exposure in utero by the Claimant, based on, as I understand it, NAS Claimants Counsel's review of the current scientific literature. The NCAM itself is in Exhibit B. The NCAM also includes studies related to opioid use or exposure. These articles are catalogued in Exhibit C.

4. The ICD Codes contained in the NCAM are what NAS Counsel believe will appear in a potential Claimant's medical billing records if there has been in utero opioid exposure of the Claimant or opioid use by the mother. I have been asked by the Trustee to review carefully these ICD Codes and determine (1) which suffice for such a determination; (2) if there are other ICD codes that I believe need to be added to the NCAM's list; and (3) to express an opinion on whether the appearance of these ICD codes in a Claimant's or the Claimant's mother's medical records is a reasonable basis to make a conclusion that the Claimant experienced in utero opioid exposure.

5. The NCAM also contains a description of NAS Counsel's recommended process to qualify a Claimant for an NAS damages recovery from the PI Trust. I have been asked to review the qualification process as well as the documents NAS Counsel recommends should be required, and to provide input regarding the scientific soundness of the qualification process. I have also been asked if, in my professional expert opinion, the NCAM and the scientific studies cataloged in Exhibit C, that are a part of it, should be shared with all Counsel representing NAS Claimants. Finally, I have been asked to provide my professional opinion on the NCAM's utility in the Claimant in utero exposure and opioid-related injury determination, and any scientific study or studies upon which I base my opinion.

6. In my capacity as a Neonatal Expert, I make the following conclusions on the basis

of my own personal knowledge. If called as a witness, I could and would competently testify to the matters stated herein. Note, that this written opinion is to be used solely for the purposes stated herein by the Trustee and does not constitute medical advice.

B. SUMMARY OF OPINION

7. I understand that there must be a finding of BOTH (A) opioid exposure and (B) consequential damage or injury, in order for a Claimant to qualify for an NAS payment from the PI Trust. Furthermore, the NCAM contains both scientifically substantiated and not scientifically substantiated information regarding qualifying as an NAS Claimant. I discuss my findings with respect to that information below.

C. BACKGROUND AND QUALIFICATIONS

8. In 1980, I received a Bachelor of Arts from Wesleyan University. I then received, in 1984, my MD from University of Illinois.

9. I am a board-certified neonatologist and have practiced for 31 years in both private and academic practices. I am board certified in Neonatal-Perinatal Medicine.

10. I am employed by Essentia Health as its Staff Neonatologist and Section Chief of Neonatology. I have devoted most of my medical practice to the provision of medical care to newborns. My curriculum vita is in Exhibit A.

11. I have served as a Medical Expert Witness for both plaintiff and defense over the course of the 15 years of my practice. Some of the cases for which I have served for the plaintiff include: 1) failure to consult a Pediatric Surgeon in a newborn with Necrotizing Enterocolitis, 2) failure to transfer a newborn with Persistent Pulmonary Hypertension of the Newborn to a center capable of performing Extracorporeal Membrane Oxygenation, 3) failure to diagnose and treat a newborn with a Subgaleal Hemorrhage, 4) failure to diagnose and treat a newborn with hypoglycemia. For the defense, I have served as an expert witness in the following cases: 1) failure to transfer a newborn with Tetralogy of Fallot to a surgical center, 2) improper resuscitation of distressed newborn due to the lack of availability of the proper equipment, 3) failure to respond an emergency phone call in a timely fashion, 4) brain injury in a newborn due to a traumatic delivery

12. My publications are in my Curriculum Vitae in Exhibit A.

13. In preparing this affidavit, I have thoroughly reviewed the NCAM, which includes the Medical Records Review Protocol, the table of ICD codes, and numerous studies pertaining to opioid use and exposure. I have also reviewed current literature that explores possible injuries caused by in utero opioid exposure.

D. FACTS AND DOCUMENTS RELIED UPON

In preparing my opinion, I reviewed and considered the following facts and documents:

1. ICD 9-10 codes related to NAS injuries
2. Assessment of Neonatal Abstinence Syndrome Surveillance-Pennsylvania, 2019
3. Neonatal Abstinence Syndrome and Maternal Opioid-Related Diagnoses in the US, 2010-2017
4. Definition of NAS
5. Diagnoses during the first three years of life for children with prenatal opioid exposure and neonatal abstinence syndrome using a large maternal infant data hub
6. Identification of Substance-Exposed Newborns and Neonatal Abstinence Syndrome Using ICD-10-CM – 15 Hospitals, Massachusetts, 2017
7. Positive Predictive Value of Administrative Data for Neonatal Abstinence Syndrome
8. Neonatal Abstinence Syndrome (NAS) – Environmental Scan and Key Informant Interview Analysis Report
9. CCDS collection: buprenorphine, hydromorphone and oxycodone
10. Declaration of Dr. KS Anand
11. Declaration of Dr. CV Howard
12. Buprenorphine Study in Rats - 2004
13. Pharmacokinetic-pharmacodynamic relationships of controlled-release oxycodone – 1996
14. Oxycodone HCl Study in Rats - 2006
15. Oxycontin Dossier – Kentucky AG
16. Oxycontin Dossier – Kentucky AG
17. Periodic Safety Update Report For: Oxycodone HCl – Purdue Pharma – 2007-2008
18. Periodic Safety Update Report For: Oxycodone HCl Preparations – Purdue Pharma – 2007-2008

19. Periodic Safety Update Report For: Oxycodone HCl Preparations Appendix – Purdue Pharma - 2009
20. Periodic Safety Update Report For: Oxycodone HCl Preparations – Purdue Pharma – 2010
21. Periodic Safety Update Report For: Oxycodone HCl Preparations – Purdue Pharma – 2011
22. Periodic Safety Update Report For: Oxycodone HCl Preparations – Purdue Pharma – 2017
23. Hydrocodone Bitartrate Investigator’s Brochure – 1996
24. OxyContin HCl Adverse Events Report – 2018
25. Upidol Uno Summary of Product Characteristics
26. OxyContin Package Insert – 1996
27. OxyContin Package Insert – 2007
28. OxyContin Package Insert – 2013
29. OxyContin Package Insert – 2014
30. OxyContin Package Insert – 2015
31. OxyContin Package Insert – 2016
32. OxyContin Package Insert – 2018
33. Maternal treatment with opioid analgesics and risk for birth defects – AmJObGyn – 2011
34. FDA NDA for Oxycodone HCl – 1994
35. CCDS timelines for buprenorphine, oxycodone and hydromorphone
36. Jackel J, et al. Emotional and Behavioral Trajectories of 2 to 9 Years Old Children Born to Opioid-Dependent Mothers. *Research on Child and Adolescent Psychopathology* 2021;49:443-457
37. Yazdy MM, et al. Periconceptional use of opioids and the risk of neural tube defects. *Obstet gynecol* 2013;122(4):838-844
38. Arter S, et al. Diagnosis during the first three years of life for children with prenatal opioid exposure and neonatal abstinence syndrome using a large maternal infant datahub. *Journal of Pediatric Nursing* 2021;61:34-39
39. Lisonkova S, et al. Neonatal abstinence syndrome and associated neonatal and maternal mortality and morbidity. *Pediatrics* 2019;144(2):e20183664
40. Harai A, et al. Neonatal abstinence syndrome and maternal opioid related diagnosis in the US 2010-2017. *JAMA* 2021;325(2):146-155

41. Lind J, et al. Maternal use of opioids during pregnancy and congenital malformations: A systematic review. *Pediatrics* 2017;139(6):e20164131
42. Azuine R, et al. Prenatal risk factors and perinatal and postnatal outcomes associated with maternal opioid exposure in an urban, low-income, multiethnic US population. *JAMA Network Open* 2019;2(6):e196405
43. Larson J, et al. Cognitive and behavioral impact on children exposed to opioids during pregnancy. *Pediatrics* 2019;144(2):e20190514
44. Wen X, et al. The Association of gestational opioid exposure and risk of major and minor congenital malformations. *JAMA Network Open* 2021;4(4):e215708
45. McGlone L, et al. *British Journal of Ophthalmology* 2014;98(2): 238-245
46. Nelson L, et al. Occurrence of strabismus in infants born to drug dependent women. *American Journal of Diseases in Children* 1987;141:(2):175-178
47. Broussard CS, et al. Maternal Treatment with opioid analgesics and risk for birth defects. *Am J Obstet Gynecol* 2011;204:314e1-11
48. Nygaard E, et al. Mental health in youth prenatally exposed to opioids and poly-drugs...*Early Human Dev* 2020;140:104910

E. EVALUATION OF THE REASONABLENESS AND SOUNDNESS OF THE NCAM BASED UPON CURRENT SCIENTIFIC KNOWLEDGE

This portion is divided into two parts, exposure and damage. As I understand it, both are required for a Claimant to qualify for a payment from the P.I. Trust. The application of these two factors to a Claimant's inclusion application is summarized below.

1. Finding Documented Opioid Exposure

In my opinion, the following will serve as definitive evidence that a newborn was exposed to an opioid in utero. This includes maternal use of Oxycodone, Hydrocodone, Oxycontin, Percocet, Fentanyl, Tramadol, Subutex, Suboxone and Methadone. All references herein to pregnancy are specifically to the pregnancy of the NAS Claimant and not any other children or any other Claimant.

1. **The mother is known to be in an Opioid Addiction Treatment Program and was treated with Methadone, Suboxone or Subutex while pregnant.**
2. **The mother admits to opioid use during pregnancy as documented in the medical record.**
3. **The mother has pharmacy records or a bottle containing an opioid reflecting she picked up an opioid during pregnancy.**
4. **A family member claims a mother was using an opioid during the pregnancy as documented in the medical record.**
5. **The maternal urine drug screen is positive for an opioid.**
6. **The newborn urine drug screen is positive for an opioid before such time as any opioids were used therapeutically.**
7. **The newborn cord toxicology screen is positive for an opioid.**
8. **The newborn meconium toxicology screen is positive for an opioid.**
9. **Any other maternally derived specimen (e.g., hair) is positive for an opioid if collected during pregnancy or within 48 hours of birth.**
10. **Any other newborn derived specimen (e.g., hair) is positive for an opioid if collected within 48 hours of birth.**

2. **Finding Substantiated Opioid Damages**

In my opinion, the damages should be accompanied by documentation of in utero opioid exposure (IUOE) and not have another identified cause. Documentation of any of the following medical, physical, cognitive or emotional conditions OR pharmacologic or non-pharmacologic treatment for IUOE indicates an opioid-related injury has occurred.

(i) Diagnosis of opioid-related injury in the NEWBORN period:

1. Neonatal Abstinence Syndrome (NAS)
2. Neonatal Opioid Withdrawal Syndrome (NOWS)
3. Use of any medication, including morphine, methadone, buprenorphine, clonidine and phenobarbital, to treat symptoms of withdrawal in a newborn. This does not include those treated after therapeutic exposure to opioids used for pain or sedation.
4. Use of any non-pharmacologic measure to treat symptoms of opioid withdrawal in a

newborn as documented in the medical record. Non-pharmacologic measures include but are not limited to:

- a. Modifying environmental stimulation –
 - 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.
 - b. Modifying feeding practices – any modification used to reduce withdrawal symptoms
 - c. Modifying support of the mother-infant dyad. This does not include those treated after therapeutic exposure to opioids used for pain or sedation.
5. Use of a published standardized 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.
 6. 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.
 7. Any exposed newborn who treated with a withdrawal treatment bundle.
 8. Diagnosis of any of the following conditions:
 - Prematurity (< 37 weeks gestation)
 - Low birth weight (< 2500 grams)
 - Congenital anomalies:
 - o Cardiac: Ventricular Septal Defect, Atrial Septal Defect, Hypoplastic Left Heart Syndrome, Pulmonary Valve Stenosis
 - o Neurologic: Neural Tube Defects, Spina bifida, anencephaly
 - o Gastrointestinal: Gastroschisis
 - o Congenital musculoskeletal deformities of skull, face and jaw
 - Cleft lip/palate
 - o Clubfoot

- Congenital deformities of hip
 - Torticollis
 - Polydactyly
 - Stillbirth
 - Hearing loss
 - Eye abnormalities – strabismus, astigmatism, nystagmus
9. Hospital length-of-stay \geq 5 days
10. Observation of any of the following **SIGNS** in newborn period (assumes other causes have been ruled out):
- Skin excoriation requiring treatment
 - Tachypnea
 - Diaper rash requiring treatment
 - Increased muscle tone
 - Excessive irritability
 - High-pitched crying
 - Reflux
 - Vomiting
 - Loose stools/diarrhea
 - Abnormal weight loss
 - Increase respiratory rate (above 60 breaths/minute)
 - Elevated temperature (above 99.5 degrees F)
 - Sweating
 - Yawning
 - Tremors
 - Convulsions/Seizures
 - Sneezing/runny nose
 - Elevated pain score
 - Feeding problems
 - Abnormal sleeping pattern

(ii) Diagnosis of opioid-related injury in the POST-NEWBORN period:

1. Growth Delay
2. Cerebral palsy
3. Attention Deficit Disorder
4. Developmental disorders of speech and language
5. Developmental Delay
6. Depressive Disorder
7. Anxiety Disorder
8. Learning Difficulties
9. Disturbances of Emotion
10. Conduct/Behavioral Disorders
11. Problems interacting with peers
12. Presence of any of the following in infancy, childhood or adolescence (assumes other causes have been ruled out):
 - 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
 - Need for special services in school

3. Scientifically Substantiated Information Contained in the NCAM

The following ICD 9 or 10 codes in the NCAM in the following 28 categories identify a newborn possibly affected by maternal opioid use (in terms of exposure or damages) and are relevant for use in the NCAM. They are scientifically based indicators of either opioid exposure, or consequential damages resulting from opioid exposure, or both. One or both

of these findings can be made based upon a review of the medical documentation pertaining to the Claimant without an ICD 9 or 10 code. However, the presence of substantiated codes, as itemized below, facilitates such a finding.

(i) NAS neonatal abstinence syndrome/opioid withdrawal

779.5 (ICD-9) – NAS Displaying withdrawal symptoms; Drug withdrawal syndrome in 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 influence affecting fetus or newborn via placenta or breast milk

P04.49 (ICD-10) – NB affected by maternal use of other drugs of addiction: NB 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 opiates: Newborn affected by maternal use of opiates (Buprenorphine, Codeine, Fentanyl, Heroin, Methadone, Morphine, Meperidine, 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 affected maternal noxious substances, unspecified

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

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

(iii) Premature Birth

765 (ICD-9) – Disorders relating to short gestation and unspecified low birthweight

765.00 (ICD-9) – Disorders relating to extreme immaturity of infant unspecified weight

765.10 (ICD-9) – Disorders relating to other preterm infants unspecified weight

P07 (ICD-10) – Disorders of newborn related to short gestation and low birthweight, not elsewhere classified

P07.00 (ICD-10) – Extremely low birth weight newborn, unspecified weight

P07.01 (ICD-10) – Extremely low birth weight newborn, less than 500 grams

P07.02 (ICD-10) – Extremely low birth weight newborn, 500-749 grams

P07.03 (ICD-10) – Extremely low birth weight newborn, 750-999 grams

- P07.1 (ICD-10) – other low birth weight newborn
- P07.10 (ICD-10) – other low birth weight newborn, unspecified weight
- P07.14 (ICD-10) – other low birth weight newborn, 1000-1249 grams
- P07.15 (ICD-10) – other low birth weight newborn, 1250-1499 grams
- P07.16 (ICD-10) – other low birth weight newborn, 1500-1749 grams
- P07.17 (ICD-10) – other low birth weight newborn, 1750-1999 grams
- P07.18 (ICD-10) – other low birth weight newborn, 2000-2499 grams
- 765.20 (ICD-9) – Unspecified weeks of gestation
- 765.09 (ICD-9) – Disorders relating to extreme prematurity of infant 2500 grams and over
- 765.19 (ICD-9) – Disorders relating to other preterm infants 2500 grams and over
- P07.2 (ICD-10) – Extreme immaturity of the newborn
- P07.20 (ICD-10) – Extreme immaturity of the newborn unspecified weeks of gestation
- P07.21 (ICD-10) – Extreme immaturity of the newborn gestational age less than 23 completed weeks
- P07.22 (ICD-10) – Extreme immaturity of the newborn gestational age 23 completed weeks
- P07.23 (ICD-10) – Extreme immaturity of the newborn gestational age 24 completed weeks
- P07.24 (ICD-10) – Extreme immaturity of the newborn gestational age 25 completed weeks
- P07.25 (ICD-10) – Extreme immaturity of the newborn gestational 26 completed weeks
- P07.26 (ICD-10) – Extreme immaturity of the newborn gestational age 27 completed weeks
- P07.3 (ICD-10) – Preterm (premature) newborn [other}
- P07.30 (ICD-10) – Preterm newborn unspecified weeks of gestation
- P07.31 (ICD-10) – Preterm newborn, gestational age 28 completed weeks
- P07.32 (ICD-10) – Preterm newborn, gestational age 29 completed weeks
- P07.33 (ICD-10) – Preterm newborn, gestational age 30 completed weeks
- P07.34 (ICD-10) – Preterm newborn, gestational age 31 completed weeks
- P07.35 (ICD-10) – Preterm newborn, gestational age 32 completed weeks
- P07.36 (ICD-10) – Preterm newborn, gestational age 33 completed weeks
- P07.37 (ICD-10) – Preterm newborn, gestational age 34 completed weeks
- P07.38 (ICD-10) – Preterm newborn, gestational age 35 completed weeks
- P07.39 (ICD-10) – Preterm newborn, gestational age 36 completed weeks

779.9 (ICD-9) – unspecified condition originating in the perinatal period

P95 (ICD-10) – stillbirth

Z37.1 (ICD-10) – stillbirth; single stillbirth

V27.1 (ICD-10) – mother with single stillborn

644 (ICD-9) – early or threatened labor

644.21 (ICD-9) – preterm labor; early onset of delivery; delivered with or without antepartum

644.2 (ICD-9) – early onset of delivery

O66 (ICD-10) – preterm labor

O60.10X1 (ICD-10) – preterm labor with preterm delivery; unspecified trimester, fetus 1

O60.12X0 (ICD-10) – preterm labor; preterm labor second trimester with preterm delivery second trimester; not applicable or unspecified

641 (ICD-9) – antepartum hemorrhage abruptio placentae and placenta previa

641.30 (ICD-9) – antepartum hemorrhage associated with coagulation defects unspecified as to episode of care

O45 (ICD-10) – premature separation of the placenta (abruptio placentae)

O45.009 (ICD-10) – premature separation of the placenta with coagulation defect, unspecified, unspecified trimester

641.21 (ICD-9) – premature separation of placenta with delivery

O45.8X1 (ICD-10) – other premature separation of placenta, first trimester

O45.8X2 (ICD-10) – other premature separation of placenta, second trimester

O45.8X3 (ICD-10) – other premature separation of placenta, third trimester

O45.9 (ICD-10) - premature separation of placenta, unspecified

O45.90 (ICD-10) - premature separation of placenta, unspecified unspecified trimester

O45.91 (ICD-10) - premature separation of placenta, unspecified first trimester

O45.92 (ICD-10) - premature separation of placenta, unspecified second trimester

O45.93 (ICD-10) - premature separation of placenta, unspecified third trimester

(iv) **Arnold Chiari Brain Malformation**

Q07 (ICD-10) – other congenital anomalies of the nervous system

Q07.01 (ICD-10) – Arnold Chiari Syndrome with spina bifida

Q07.03 (ICD-10) – Arnold Chiari Syndrome with spina bifida and hydrocephalus

Q07.8 (ICD-10) – other specified congenital malformations of nervous system

Q07.9 (ICD-10) – congenital malformations of nervous system, unspecified

740 (ICD – 9) – anencephalus

Q00 (ICD-10) – anencephaly with similar malformations

Q00.0 (ICD-10) – anencephaly

742.1 (ICD-9) – microcephalus

Q02 (ICD-10) - microcephaly

756 (ICD-9) – congenital anomalies of skull and face bones

Q04.8 (ICD-10) – other specified congenital malformations of brain

742.9 (ICD-9) – unspecified congenital anomaly of brain spinal cord and nervous system

Q04.9 (ICD-10) – congenital malformation of brain, unspecified

779.1 (ICD-9) – other and unspecified cerebral irritability in newborn

P91.88 (ICD-10) – other specified disturbances of cerebral status of newborn

780.39 (ICD-9) – other convulsions

779.0 (ICD-9) – convulsions in newborn

R56.9 (ICD-9) – unspecified convulsions

(v) **Cerebral Palsy**

343 (ICD-9) – cerebral palsy

343.9 (ICD-9) – infantile cerebral palsy unspecified

343.8 (ICD-9) – other specified infantile cerebral palsy

G80 (ICD-10) – cerebral palsy

G80.9 (ICD-10) – cerebral palsy, unspecified

G80.1 (ICD-10) – spastic diplegic cerebral palsy

(vi) **Club Foot**

M21.179 (ICD-10) – varus deformity. NEC (not elsewhere classified), unspecified ankle

754.50 (ICD-9) – congenital talipes varus

754.51 (ICD-9) – congenital talipes equinovarus

Q66.0 (ICD-10) - congenital talipes equinovarus

Q66.00 (ICD-10) - congenital talipes equinovarus, unspecified foot

Q66.01 (ICD-10) - congenital talipes equinovarus, right foot

Q66.02 (ICD-10) - congenital talipes equinovarus, left foot

745.70 (ICD-9) – talipes unspecified

Q66.89 (ICD-10) – other specified congenital deformities of feet

(vii) Cleft Palate

749 (ICD-9) – cleft palate and lip

Q35 (ICD-10) – cleft palate

Q35.9 (ICD-10) – cleft palate unspecified

749.00 (ICD-9) – cleft palate unspecified

749.10 (ICD-9) – cleft lip unspecified

Q36 (ICD-10) – cleft lip

Q36.9 (ICD-10) – cleft lip unilateral

749.20 (ICD-9) - cleft palate with cleft lip unspecified

Q37 (ICD-10) – cleft palate with cleft lip

Q37.9 (ICD-10) – unspecified cleft palate with unilateral cleft lip

749.25 (ICD-9) – other combinations of cleft palate with cleft lip

Q38.5 (ICD-10) – congenital malformations of palate, NEC

(viii) Congenital Deformations

Q65.8 (ICD-10) - other congenital deformities of hip

Q65.89 (ICD-10) - other specified congenital deformities of hip

Q65.9 (ICD-10) - congenital deformity of hip unspecified

754 (ICD-9) – certain congenital musculoskeletal deformities

754.0 (ICD-9) - congenital musculoskeletal deformities of skull, face, and jaw

754.1 (ICD-9) - congenital musculoskeletal deformities of sternocleidomastoid muscle

754.3 (ICD-9) - congenital dislocation of hip

755.63 (ICD-9) - other congenital deformities of hip

(ix) Gastroschisis

756.73 (ICD-9) – gastroschisis (no anus)

Q79.3 (ICD-10) – gastroschisis (no anus)

(x) Head/Neck

784.99 (ICD-9) – other symptoms involving head and neck

781.0 (ICD-9) – abnormal head movements

R25.0 (ICD-10) – abnormal head movements

(xi) Hearing Problems

389 (ICD-9) – hearing loss

H90 (ICD-10) – conductive and sensorineural hearing loss

H90.0 (ICD-10) – conductive hearing loss, bilateral

H90.2 (ICD-10) – conductive hearing loss, unspecified

389.1 (ICD-9) – sensorineural hearing loss

H90.3 (ICD-10) – sensorineural hearing loss, bilateral

H90.5 (ICD-10) – unspecified sensorineural hearing loss

389.2 (ICD-9) – mixed conductive and sensorineural hearing loss

H90.6 (ICD-10) - mixed conductive and sensorineural hearing loss, bilateral

H90.8 (ICD-10) - mixed conductive and sensorineural hearing loss, unspecified

389.7 (ICD-9) – deaf nonspeaking (NEC)

H91.3 (ICD-10) – deaf nonspeaking (NEC)

389.8 (ICD-9) – hearing loss NEC: other specified forms of hearing loss

H91.8X1 (ICD-10) – other specified hearing loss, right ear

H91.8X2 (ICD-10) – other specified hearing loss, left ear

H91.8X1 (ICD-10) – other specified hearing loss, both ears

389.9 (ICD-9) – hearing loss NEC; unspecified hearing loss

388.8 (ICD-9) - other disorders of ear

H91.90 (ICD-10) – unspecified hearing loss, unspecified ear

H93.8X1 (ICD-10) - other specified disorders of right ear

H93.8X2 (ICD-10) - other specified disorders of left ear

H93.8X3 (ICD-10) - other specified disorders of ear, bilateral

H93.8X9 (ICD-10) - other specified disorders of ear, unspecified ear

H93.90 (ICD-10) - unspecified disorder of ear, unspecified ear

(xii) Heart Defects

745 (ICD-9) – bulbus cordis anomalies and anomalies of cardiac septal closure

745.4 (ICD-9) - ventricular septal defect

Q21 (ICD-10) - congenital malformations of cardiac septa

Q21.0 (ICD-10) - ventricular septal defect

745.5 (ICD-9) - ostium secundum type atrial septal defect

Q21.1 (ICD-10) - atrial septal defect

745.9 (ICD-9) - unspecified defect of septal closure

Q21.9 (ICD-10) - congenital malformation of cardiac septum, unspecified

Q22 (ICD-10) - congenital malformations of pulmonary and tricuspid valves

Q22.1 (ICD-10) - congenital pulmonary valve stenosis

I37.2 (ICD-10) - nonrheumatic pulmonary valve stenosis with insufficiency

I37.8 (ICD-10) - other nonrheumatic pulmonary valve disorders

I37.9 (ICD-10) - nonrheumatic pulmonary valve disorder, unspecified

Q28.9 (ICD-10) - congenital malformation of circulatory system, unspecified

746 (ICD-9) - other congenital anomalies of heart

746.89 (ICD-9) - other specified congenital anomalies of heart

746.9 (ICD-9) - unspecified congenital anomaly of heart

Q24 (ICD-10) - other congenital malformations of heart

Q24.8 (ICD-10) - other specified congenital malformations of heart

Q24.9 (ICD-10) - congenital malformations of heart, unspecified

785.9 (ICD-9) - other symptoms involving cardiovascular system

R09.89 (ICD-9) - other specified symptoms and signs involving the circulatory and respiratory systems

P29 (ICD-10) - cardiovascular disorders originating in the perinatal period

747 (ICD-9) - other congenital anomalies of circulatory system

747.9 (ICD-9) - unspecified congenital anomaly of circulatory system

P29.89 (ICD-10) - other cardiovascular disorders originating in the perinatal period

(xiii) Diarrhea/Gastrointestinal Disorders

K92.9 (ICD-10) - gastrointestinal disorders; disease of digestive system, unspecified

586.9 (ICD-9) - other specified disorders of intestines

K92.89 (ICD-10) - other specified diseases of the digestive system

564 (ICD-9) - functioning digestive disorders NEC

K59 (ICD-10) - other functional intestinal disorders

787.91 (ICD-9) – diarrhea

R19 (ICD-10) - other symptoms and signs involving the digestive system and abdomen

R19.7 (ICD-10) - diarrhea, unspecified

K58.0 (ICD-10) - Irritable bowel; Irritable bowel syndrome with diarrhea

K52 (ICD-10) - other and unspecified noninfective gastroenteritis and colitis

K52.89 (ICD-10) - other specified noninfective gastroenteritis and colitis

777 (ICD-9) - perinatal disorders of digestive system

691.0 (ICD-9) - diaper or napkin rash

L22 (ICD-10) - diaper dermatitis

(xiv) Missing or additional fingers or toes

Q69 (ICD-10) - polydactyly

755.0 (ICD 9) - polydactyly unspecified digits

Q69.9 (ICD-10) - polydactyly unspecified

755.01 (ICD-9) - polydactyly of fingers

755.02 (ICD-9) – polydactyly of toes

Q69.0 (ICD-10) - accessory finger(s)

P94.9 (ICD-10) - disorder of muscle tone, unspecified

(xv) Respiratory Problems/Asthma

769 (ICD-9) - respiratory distress syndrome in newborn

P22.0 (ICD-10) - respiratory distress syndrome of newborn

P28.1 (ICD-10) - transient tachypnea of newborn

P28.5 (ICD-10) - respiratory failure of newborn

770.6 (ICD-9) - transient tachypnea of newborn

770.11 (ICD-9) - meconium aspiration without respiratory symptoms

P24.00 (ICD-10) - meconium aspiration without respiratory symptoms

770.12 (ICD-9) - meconium aspiration with respiratory symptoms

P24.01 (ICD-10) - meconium aspiration with respiratory symptoms

770.89 (ICD-9) - other respiratory problems after birth

P22.8 (ICD-10) - other respiratory distress of newborn

P22.9 (ICD-10) - respiratory distress of newborn, unspecified
770.17 (ICD-9) - other fetal and newborn aspiration without respiratory symptoms
P24.80 (ICD-10) - other neonatal aspiration without respiratory symptoms
770.18 (ICD-9) - other fetal and newborn aspiration with respiratory symptoms
P24.81 (ICD-10) - other neonatal aspiration with respiratory symptoms
P782.5 (ICD-9) – cyanosis
R23.0 (ICD-10) – cyanosis
770.83 (ICD-9) - cyanotic attacks of newborn
R28.2 (ICD-10) - cyanotic attacks of newborn
770.84 (ICD-9) - respiratory failure of newborn
770.9 (ICD-9) - unspecified respiratory condition of fetus and newborn
P28.5 (ICD-10) - respiratory failure of newborn
P28.9 (ICD-10) - respiratory condition of newborn, unspecified
R06 (ICD-10) - abnormalities of breathing
R06.8 (ICD 10) - other abnormalities of breathing
R06.7 (ICD-10) - sneezing
R09.02 (ICD-10) – hypoxemia
R09.81 (ICD-10) - nasal congestion
519 (ICD-9) - other diseases of respiratory system
519.8 (ICD-9) - other diseases of respiratory system NEC
493 (ICD-9) - asthma
493.00 (ICD-9) - extrinsic asthma unspecified
493.10 (ICD-9) - intrinsic asthma unspecified
493.90 (ICD-9) - asthma unspecified
J45 (ICD-10) - asthma
J45.20 (ICD-10) - mild intermittent asthma, uncomplicated
J45.21 (ICD-10) - mild intermittent asthma, with (acute) exacerbation
J45.22 (ICD-10) - mild intermittent asthma, with status asthmaticus
J45.30 (ICD-10) - mild persistent asthma, uncomplicated
J45.50 (ICD-10) - severe persistent asthma, uncomplicated

J45.40 (ICD-10) - moderate persistent asthma, uncomplicated

(xvi) Serious Vision Problems

V41.0 (ICD-9) – problems with sight

743.8 (ICD-9) - other specified anomalies of eye congenital

369.9 ICD 9 unspecified visual loss

Q15 (ICD-10) - other congenital malformations of eye

Q15.8 (ICD-10) - other specified congenital malformations of eye

743.9 (ICD-9) - unspecified anomaly of eye congenital

Q15.9 (ICD-10) - congenital malformation of eye unspecified

368 (ICD-9) - visual disturbances

H53 (ICD-10) - visual disturbances

H53.031 (ICD-10) - strabismic amblyopia right eye

H53.031 (ICD-10) - strabismic amblyopia left eye

H53.033 (ICD-10) - strabismic amblyopia bilateral

H53.039 (ICD-10) - strabismic amblyopia unspecified eye

378 (ICD-9) - strabismus and other disorders of binocular eye movements

378.3 (ICD-9) – strabismus

H50 (ICD-10) - other strabismus

H50.89 (ICD-10) - other specified strabismus

H50.9 (ICD-10) - unspecified strabismus

378.41 (ICD-9) – Esophoria

H50.51 (ICD-10) – Esophoria

378.2 (ICD-9) – Intermittent esophoria alternating

H50.32 (ICD-10) - Intermittent alternating esophoria

378.35 (ICD-9) - Accommodative component in esophoria

H50.43 (ICD-10) - Accommodative component in esophoria

378.42 (ICD-9) – Exophoria

H50.52 (ICD-10) – Exophoria

378.24 (ICD-9) - Intermittent exophoria alternating

H50.34 (ICD-10) - Intermittent alternating exophoria

379 (ICD-9) - Other disorders of eye

379.50 (ICD-9) - unspecified

H55 (ICD-10) - Nystagmus; Nystagmus and other irregular eye movements

H55.00 (ICD-10) - Nystagmus; unspecified nystagmus

379.51 (ICD-9) - Congenital nystagmus

H55.01 (ICD-10) - Nystagmus; Congenital nystagmus

379.56 (ICD-9) - Other forms of nystagmus

H55.09 (ICD-10) - Other forms of nystagmus

379.59 (ICD-9) - Other irregularities of eye movements

H55.89 (ICD-10) - other irregular eye movements

(xvii) Skin Conditions

P83.9 (ICD-10) - Includes diaper rash, skin excoriation, blisters

778.8 (ICD-9) - Includes diaper rash skin excoriation, blisters

(xviii) Spina Bifida

741 (ICD-9) – spina bifida

741.9 (ICD-9) – spina bifida: without mention of hydrocephalus

741.90 (ICD-9) – spina bifida: unspecified region without hydrocephalus

Q05 (ICD-10) – Spina bifida

Q05.8 (ICD-10) – Spina bifida; sacral spina bifida without hydrocephalus

Q05.9 (ICD-10) – Spina bifida; spina bifida unspecified

741.93 (ICD-9) – Spina bifida lumbar region without hydrocephalus

Q05.7 (ICD-10) – Spina bifida; lumbar spina bifida without hydrocephalus

741.00 (ICD-9) – Spina bifida unspecified region with hydrocephalus

Q05.4 (ICD-10) – unspecified spina bifida with hydrocephalus

741.03 (ICD-9) – Spina bifida lumbar region with hydrocephalus

Q05.2 (ICD-10) – lumbar spina bifida with hydrocephalus

Q05.3 (ICD-10) – sacral spina bifida without hydrocephalus

(xix) Unexplained and unresolved acid reflux (unresponsive to medication)

787.1 (ICD-9) - Heartburn; Heartburn

R12 (ICD-10) – Heartburn

530.11 (ICD-9) - Reflux esophagitis

530.81 (ICD-9) - esophageal reflux

K21 (ICD-10) - Gastroesophageal reflux disease

K21.9 (ICD-10) - Gastroesophageal reflux disease without esophagitis

K21.0 (ICD-10) - Gastroesophageal reflux disease with esophagitis

536.8 (ICD-9) – dyspepsia; dyspepsia and other specified disorders of function of stomach

K30 (ICD-10) - functional dyspepsia (indigestion)

(xx) Difficulty swallowing, breastfeeding or bottle-feeding

779.3 (ICD-9) - Disorder of stomach function and feeding problems in newborn

779.31 (ICD-9) - Feeding problems in newborn

783.3 (ICD-9) - Feeding difficulties and mismanagement

783.9 (ICD-9) - Other problems concerning nutrition, metabolism and development

R63.3 (ICD-10) - Feeding problem

R63.8 (ICD-10) - Other symptoms concerning nutrition, metabolism and development

P92 (ICD-10) - Feeding problems of newborn

F98.29 (ICD-10) - Other feeding disorders of infancy and early childhood

P92.1 (ICD-10) - regurgitation and rumination of newborn

P92.2 (ICD-10) - Slow feeding of newborn

P92.3 (ICD-10) – Underfeeding of newborn

P92.5 (ICD-10) - neonatal difficulty feeding at breast

P92.8 (ICD-10) - Other feeding problems of newborn

P92.9 (ICD-10) - Slow feeding of newborn

787.2 (ICD-9) - Dysphagia; Dysphagia, other

787.20 (ICD-9) - Dysphagia; Dysphagia, Unspecified

R13 (ICD-10) – Aphagia and Dysphagia

R13.0 (ICD-10) – Aphagia; Aphagia

R13.11 (ICD-10) – Dysphagia; Dysphagia, oral phase

R13.12 (ICD-10) – Dysphagia; Dysphagia, oropharyngeal phase

R13.13 (ICD-10) – dysphagia, pharyngeal; Dysphagia, and pharyngeal phase

R13.14 (ICD-10) - dysphagia, pharyngealesoph; Dysphagia, pharyngoesophageal phase

P92.0 (ICD-10) - vomiting; Vomiting of newborn

P92.09 (ICD-10) - other vomiting of newborn

787.0 (ICD-9) - nausea and vomiting

787.01 (ICD-9) - nausea and vomiting

787.03 (ICD-9) - vomiting alone

R11.2 (ICD-10) - nausea with vomiting, unspecified

R11.11 (ICD-10) - vomiting without nausea

P74.1 (ICD-10) - dehydration of newborn

P92.6 (ICD-10) - failure to thrive in newborn

R63.4 (ICD-10) - abnormal weight loss

R63.6 (ICD-10) – underweight

R68.11 (ICD-10) - excessive crying of infant (baby)

R68.12 (ICD-10) - fussy infant (baby)

750.25 (ICD 9) - congenital fistula of lip

770.85 (ICD-9) - aspiration of postnatal stomach contents without respiratory symptoms

P24.30 (ICD-10) – neonatal aspiration of milk and regurgitated food without respiratory symptoms

770.63 (ICD-9) - aspiration of postnatal stomach contents with respiratory symptoms

P24.31 (ICD-10) - neonatal aspiration of milk and regurgitated food with respiratory symptoms

(xxi) Attention problems/Inability to focus (incl ADD & ADHD)

314.00 (ICD-9) - attention deficit disorder of childhood without hyperactivity

314.01 (ICD-9) - attention deficit disorder of childhood with hyperactivity

F90.1 (ICD-10) - attention deficit hyperactivity disorder predominantly inattentive type

F90.2 (ICD-10) - attention deficit hyperactivity disorder, combined type

F90.8 (ICD-10) - attention deficit hyperactivity disorder other type

314.1 (ICD-9) - hyperkinesis of childhood with developmental delay

F90.9 (ICD-10) - attention deficit hyperactivity disorder, unspecified

799.51 (ICD-9) - attention or concentration deficit

F90.0 (ICD-10) - attention deficit hyperactivity disorder, predominantly inattentive type

R41.840 (ICD-10) - inattention; Attention and concentration deficit

(xxii) Autism

299.0 (ICD-9) – Infantile autism

299.00 (ICD-9) – Infantile autism current or active state

F84.0 (ICD-10) - autistic disorder

F84.1 (ICD-10) - atypical autism

299.01 (ICD-9) - infantile autism residual state

299.10 (ICD-9) – disintegrative psychosis current or active state

299.11 (ICD-9) - disintegrative psychosis residual state

(xxiii) Delay or inability to talk

315.31 (ICD-9) - developmental language disorder

F80 (ICD-10) - specific developmental disorders of speech and language

F80.1 (ICD-10) - expressive language disorder

315.2 (ICD-9) - receptive language disorder (mixed)

H93.25 (ICD-10) - central auditory processing disorder

F80.2 (ICD-10) - mixed receptive-expressive language disorder

315.34 (ICD-9) - speech and language developmental delay due to hearing loss

F80.4 (ICD-10) - speech and language developmental delay due to hearing loss

315.35 (ICD-9) - child onset fluency disorder

F80.81 (ICD-10) - child onset fluency disorder

315.39 (ICD-9) - other developmental speech disorder

F80.0 (ICD-10) - phonological disorder

F80.89 (ICD-10) - other developmental disorders of speech and language

F80.9 (ICD-10) - developmental disorder of speech and language, unspecified

(xxiv) Delay or Inability to walk

315.4 (ICD-9) - developmental coordination disorder

F82 (ICD-10) - specific developmental disorder of motor function

781.2 (ICD-9) - abnormality of gait

R26 (ICD-10) - abnormalities of gait and mobility

719.7 (ICD-9) - difficulty in walking NEC

R26.2 (ICD-10) - difficulty in walking NEC

R26.89 (ICD-10) - other abnormalities of gait and mobility

781.3 (ICD-9) - lack of coordination

R27.8 (ICD-10) - other lack of coordination

(xxv) Depression

296.82 (ICD-9) - typical depressive disorder

311 (ICD-9) - depressive disorder not elsewhere classified

F32.9 (ICD-10) - major depressive disorder, single episode, unspecified

296.20 (ICD-9) - major depressive affective disorder single episode unspecified degree

311 (ICD-9) - depressive disorder not elsewhere classified

F32.9 (ICD-10) - major depressive disorder, single episode, unspecified

296.31 (ICD-9) - major depressive affective disorder recurrent episode mild degree

F33 (ICD-10) - major depressive disorder, recurrent

F33.0 (ICD-10) - major depressive disorder, recurrent, mild

F33.4 (ICD-10) - major depressive disorder, recurrent, and remission

F33.8 (ICD-10) - other recurrent depressive disorders

F34 (ICD-10) - persistent mood [affective] disorders

F34.8 (ICD-10) - other persistent mood [affective] disorders

F34.81 (ICD-10) - disruptive mood dysregulation disorder

F34.9 (ICD-10) - persistent mood [affective] disorder, unspecified

296.90 (ICD-10) - mood disorder NOS

F39 (ICD-10) - unspecified mood [affective] disorder

300 (ICD-9) - neurotic disorders

F41 (ICD-10) - other anxiety disorders

F41.9 (ICD-10) anxiety disorder, unspecified

300.01 (ICD-9) - panic disorder

F41.0 (ICD-10) - panic disorder [episodic paroxysmal anxiety]

F43.21 (ICD-10) – adjustment disorder with depressed mood

301.89 (ICD-9) - other personality disorders

F60 (ICD-10) - specific personality disorders

F60.89 ICD-10 other specific personality disorders

(xxvi) Growth/Developmental delays

783.42 (ICD-9) - delayed milestones

R62 (ICD-10) - lack of expected normal physiological development in childhood and adults

R62.0 (ICD-10) - delayed milestone in childhood

783.41 (ICD-9) - failure to thrive

R62.50 (ICD-10) - Unspecified lack of expected normal physiological development in childhood

R62.51 (ICD-10) - failure to thrive (child)

783.43 (ICD-9) - short stature

R62.52 (ICD-10) - short stature (child)

783.40 (ICD-9) - unspecified lack of expected normal physiological development

R62.59 (ICD-10) - other lack of expected normal physiological development in childhood

(xxvii) Learning disability/Cognitive delays

315.2 (ICD-9) - other specific developmental learning difficulties

F81 (ICD-10) - specific developmental disorders of scholastic skills

F81.89 (ICD-10) - other developmental disorders of scholastic skills

Z13.4 (ICD-10) - encounter for screening for global developmental delays

V79.3 (ICD-9) - encounter for screening for global developmental delays

Z13.42 (ICD-10) - encounter for screening for global developmental delays (milestones)

315.9 (ICD-9) - unspecified delay in development

V40 (ICD-9) - mental and behavioral problems with learning

F81.9 (ICD-10) - developmental disorder of scholastic skills, unspecified

315.00 (ICD-9) - developmental reading disorder unspecified

F81.0 (ICD-10) - specified reading disorder

315.01 (ICD-9) – alexia

315.02 (ICD-9) - developmental dyslexia

315.09 (ICD-9) - other specific developmental reading disorder

R48 (ICD-10) - dyslexia and other symbolic dysfunctions, NEC

R48.0 (ICD-10) - dyslexia and alexia

315.1 (ICD-9) - developmental arithmetical disorder

315.8 (ICD-9) - other specified delays in development

F88 (ICD-10) - other disorders of psychological development

317 (ICD-9) - mild intellectual disabilities

F70 (ICD-10) - mild intellectual disabilities

318 (ICD-9) - other specified mental retardation

318.1 (ICD-9) - severe intellectual disabilities

F72 (ICD-10) - severe and intellectual disabilities

318.2 (ICD-9) - profound intellectual disabilities

F73 (ICD-10) - profound intellectual disabilities

799.52 (ICD-9) - cognitive communication deficit

R41.841 (ICD-10) - cognitive communication deficit

799.59 (ICD-9) - other signs and symptoms involving cognition

R41.83 (ICD-10) - borderline intellectual functioning

R41.89 (ICD-10) - other symptoms and signs involving cognitive functions and awareness

(xxviii) Social/behavioral difficulty or delays (including aggressiveness or poor)

313 (ICD-9) - disturbances of emotions specific to childhood and adolescence

313.2 (ICD-9) - introverted disorder of childhood

F93 (ICD-10) - emotional disorders with onset specific to childhood

F93.8 (ICD-10) - other childhood emotional disorders

313.23 (ICD-9) - selective mutism; Elective mutism specific to childhood and adolescence

F94 (ICD-10) - disorders of social functioning with onset specific to childhood and adolescence

F94.0 (ICD-10) - selective mutism

313.81 (ICD-9) - Oppositional defiant disorder; Oppositional disorder of childhood or adolescence

F91 (ICD-10) - conduct disorders

F91.3 (ICD-10) - oppositional defiant disorder

313.89 (ICD-9) - other emotional disorders of childhood or adolescence

F94.9 (ICD-10) - childhood disorder of social functioning, unspecified

F98.0 (ICD-10) - Enuresis not due to a substance or known physiological condition

F98.1 (ICD-10) - Encopresis not due to a substance or known physiological condition

F98.3 (ICD-10) - Pica of infancy or childhood

F98.8 (ICD-10) - other specified behavioral and emotional disorders with onset usually occurring in childhood and adolescence

313.9 (ICD-9) – unspecified emotional disturbance of childhood or adolescence

F93.9 (ICD-10) - childhood emotional disorder, unspecified

F94.8 (ICD-10) - other childhood disorders of social functioning

F98.9 (ICD-10) - unspecified behavioral and emotional disorders with onset usually occurring in childhood and adolescence

312.00 (ICD-9) - undersocialized conduct disorder aggressive type unspecified degree

312 (ICD-9) - disturbance of conduct NEC

312.20 (ICD-9) - socialized conduct disorder unspecified degree

F91.2 (ICD-10) - conduct disorder, adolescent onset type

312.30 (ICD-9) - impulse control disorder, unspecified

F63 (ICD-10) - impulse disorders

F63.9 (ICD-10) - impulse disorder, unspecified

312.34 (ICD-9) - intermittent explosive disorder

F63.81 (ICD-10) - intermittent explosive disorder

312.39 (ICD-9) - other disorders of impulse control

F63.89 (ICD-10) - other impulse disorders

312.39 (ICD-9) - other disorders of impulse control

F63.89 (ICD-10) - other impulse disorders

312.81 (ICD-9) - conduct disorder childhood onset type

F91.1 (ICD-10) – conduct disorder, childhood onset type

312.82 (ICD-9) - conduct disorder adolescent onset type

799.89 (ICD-9) - other ill-defined conditions

R46 (ICD-10) - symptoms and signs involving appearance and behavior

46.81 (ICD-10) – obsessive-compulsive behavior

R46.89 (ICD-10) - other symptoms and signs involving appearance and behavior

304 (ICD-9) - drug dependence

304.0 (ICD-9) - opioid type dependence

304.90 (ICD-9) - substance abuse; Unspecified drug dependence, unspecified use

F19.20 (ICD-10) - other psychoactive substance dependence, uncomplicated

303 (ICD-9) - alcohol dependence syndrome

303.90 (ICD-9) - other and unspecified alcohol dependence unspecified drinking behavior

F10 (ICD-10) - alcohol related disorders

F10.20 (ICD-10) - alcohol dependence uncomplicated

304.00 (ICD-9) - opioid type dependence unspecified use

F11 (ICD-10) - opioid related disorders

F11.20 (ICD-10) - opioid dependence, uncomplicated

4. **Information Contained in the NCAM Apparently Not Currently Scientifically Substantiated**

In my opinion, based upon the current state of scientific research, the following ICD-9 and ICD-10 Codes listed in the NCAM, in the following 19 categories, cannot be said to establish opioid exposure or damage, according to the current state of the scientific literature. However, this conclusion is subject to the qualifications described in A-2, above.

(i) **NAS (neonatal abstinence syndrome/opioid withdrawal)**

P96.2 (ICD-10) – withdrawal symptoms with therapeutic use of drugs in newborn

Z92.29 (ICD-10) – personal history of other drug therapy

Z87.898 (ICD-10) – personal history of other specified conditions

V13.89 (ICD-10) - personal history of other specified diseases

V13.89 (ICD-9) - personal history of other specified conditions

(ii) **IUDE (in utero drug exposure)**

648.32 (ICD-9) – drug dependence of mother, delivered, with mention of postpartum complication

Q86.8 (ICD-10) – other congenital malformation syndromes due to known exogenous causes

V87.49 (ICD-9) – personal history of other drug therapy

V13.89 (ICD-9) – personal history of other specified diseases

Q89.9 (ICD-10) – congenital malformation unspecified

P04.1 (ICD-10) – newborn affected by other maternal medications

796.0 (ICD-9) – nonspecific abnormal toxicologic findings

R82.5 (ICD-10) – elevated urine levels of drugs, medicaments and biological substances

R89.2 (ICD-10) – elevated levels of drugs, medicaments and biological substances from other organs, systems and tissues

035.5XX0 – Maternal care for (suspected) damage to fetus by drugs

(iii) Premature Birth

641.30 (ICD-9) – antepartum hemorrhage associated with coagulation defects unspecified as to episode of care

762.6 (ICD-9) – other and unspecified conditions of the umbilical cord affecting fetus or newborn

P02.69 (ICD-10) – newborn affected by other conditions of umbilical cord

O36.83 (ICD-10) – maternal care for abnormalities of fetal heart rate or rhythm

(iv) Arnold Chiari Brain Malformation

Q75.3 (ICD-9) – macrocephaly

Q04 (ICD-10) - other congenital malformations of brain

Q04.8 (ICD-10) - other specified congenital malformations of brain

Q04.9 (ICD-10) – congenital malformation of brain, unspecified

(v) Cerebral Palsy

G80.4 (ICD-10) - Ataxic cerebral palsy

342 (ICD-9) - hemiplegia and hemiparesis

342.8 (ICD-9) - other specified hemiplegia and hemiparesis affecting unspecified side

G81 (ICD-10) - hemiplegia and hemiparesis

(vi) Club Foot

M21.549 (ICD-10) - acquired clubfoot, unspecified foot

M21.179 (ICD-10) - acquired clubfoot, left foot

M21.541 (ICD-10) - acquired club foot right foot

Q66.10 (ICD-10) - congenital talipes calcaneovarus, unspecified foot

Q66.11 (ICD-10) - congenital talipes calcaneovarus, right foot

Q66.12 (ICD-10) - congenital talipes calcaneovarus, left foot

754.6 (ICD-9) - congenital talipes valgus

Q66.40 (ICD-10) - congenital talipes calcaneovalgus, unspecified foot

Q66.41 (ICD-10) - congenital talipes calcaneovalgus, right foot

Q66.2 (ICD-10) - congenital talipes calcaneovalgus, left foot

754.70 (ICD-9) - talipes unspecified

(vii) Hearing Problems

381 (ICD-9) - non separative otitis media and eustachian tube disorders

381.01 (ICD-9) - acute serous otitis media

381.50 (ICD-9) - eustachian salpingitis unspecified

381.51 (ICD-9) - acute eustachian salpingitis

381.52 (ICD-9) - chronic eustachian salpingitis

H65 (ICD-10) - nonsuppurative otitis media

H65.00 (ICD-10) - acute otitis media; Acute serous otitis media, unspecified ear

H65.01 (ICD-10) - Acute serous otitis media, right ear

H65.07 (ICD-10) - Acute serous otitis media, recurrent, unspecified ear

381.00 (ICD-9) - acute nonsuppurative otitis media, unspecified

H65.197 (ICD-10) - acute nonsuppurative otitis media, recurrent, unspecified ear

H65.199 (ICD-10) - other acute nonsuppurative otitis media, unspecified ear

380 (ICD-9) - disorders of external ear

380.8 (ICD-9) - other disorders of external ear

380.10 (ICD-9) - infective otitis externa, unspecified

H60.393 (ICD-10) - other infective otitis externa, bilateral

382 (ICD-9) - suppurative and unspecified otitis media

382.00 (ICD-9) - acute suppurative otitis media without spontaneous rupture of eardrum

H66 (ICD-10) - suppurative and unspecified otitis media

H66.001 (ICD-10) – acute suppurative otitis media without spontaneous rupture of eardrum, right ear

382.9 (ICD-9) - unspecified otitis media

H66.90 (ICD-10) - otitis media, unspecified, unspecified ear

388 (ICD-9) - other disorders of ear

388.7 (ICD-9) - otalgia, unspecified

H92 (ICD-10) - otalgia and effusion of ear

H92.03 (ICD-10) - otalgia, bilateral

380.22 (ICD-9) - other acute otitis externa

H60 (ICD-10) - otitis externa

H60.502 (ICD-10) - unspecified acute noninfective otitis externa, left ear

(viii) **Heart Defects**

- Q20 (ICD-10) - Congenital malformations of cardiac chambers and connections
- Q20.5 (ICD-10) - Transposition of the great arteries; Discordant atrioventricular connection
- Q20.8 (ICD-10) - other congenital malformations of cardiac chambers and connections
- Q20.9 (ICD-10) – Congenital malformation of cardiac chambers and connections, unspecified
- Q25 (ICD-10) - congenital malformations of great arteries
- Q25.0 (ICD-10) - patent ductus arteriosus
- Q25.8 (ICD-10) - other congenital malformations of other great arteries
- Q25.9 (ICD-10) - congenital malformation of great arteries, unspecified
- Q26 (ICD-10) congenital malformations of great veins
- Q26.8 (ICD-10) - other congenital malformations of great veins
- Q26.9 (ICD-10) - congenital malformations of great vein, unspecified

(ix) **Irritable bowel problems/Chronic diarrhea/Gastrointestinal disorders**

- 564.00 (ICD-9) - Unspecified Constipation
- K59.00 (ICD-10) - Constipation; Constipation unspecified
- K58 (ICD-10) -Irritable bowel syndrome
- 564.1 (ICD-9) - irritable bowel syndrome
- K58.9 (ICD-10) - Irritable bowel; Irritable bowel syndrome without diarrhea
- 787.3 (ICD-9) – flatulence/eructation/gas pain; Flatulence, irritation, and gas pain
- R14 (ICD-10) - Abdominal distention (gaseous)
- R14.1 (ICD-10) - Gas pain
- R14.2 (ICD-10) – eructation
- R14.3 (ICD-10) – flatulence
- 787.5 (ICD-9) - Abnormal bowel sounds
- R19.11 (ICD-10) - Absent bowel sounds
- R19.12 (ICD-10) - hyperactive bowel sounds
- R19.15 (ICD-10) - Other abnormal bowel sounds
- K42 (ICD-10) - umbilical hernia
- K42.9 (ICD-10) - Hernia, umbilical, without obstruction or gangrene
- 777.50 (ICD-9) - Necrotizing enterocolitis in newborn; Necrotizing enterocolitis in newborn,

unspecified

P77 (ICD-10) - Necrotizing enterocolitis of newborn

P77.1 (ICD-10) – Stage 1 Necrotizing enterocolitis of newborn

P77.2 (ICD-10) – Stage 2 Necrotizing enterocolitis of newborn

P77.3 (ICD-10) – Stage 3 Necrotizing enterocolitis of newborn

P77.9 (ICD-10) - Necrotizing enterocolitis of newborn, unspecified

751.2 (ICD-9) - Congenital absence, atresia, and stenosis of large intestine, rectum and anal canal

Q42 (ICD-10) - Congenital absence, atresia, and stenosis large intestine

Q42.2 (ICD-10) - Congenital absence, atresia, and stenosis of anus with fistula

Q42.3 (ICD-10) - Congenital absence, atresia, and stenosis of anus without fistula

789.07 (ICD-9) - Abdominal pain generalized

789.00 (ICD-9) - abdominal pain unspecified site

R10.0 (ICD-10) - Acute abdomen

789.09 (ICD-9) - Abdominal pain other specified site

788 (ICD-9) - Symptoms involving urinary system

788.3 (ICD-9) - urinary incontinence unspecified

R32 (ICD-10) - unspecified urinary incontinence

788.1 (ICD-9) – dysuria

R30 (ICD-10) - Pain associated with micturition

R30.0 (ICD-10) – dysuria

599 (ICD-9) - Other disorders of urethra and urinary tract

599.0 (ICD-9) - Urinary tract infection, site not specified

N39 (ICD-10) - Other disorders of urinary system

N39.0 (ICD-10) - Urinary tract infection, site not specified

592 (ICD-9) - Calculus of kidney and ureter

592.0 (ICD-9) - Calculus of kidney

N20 (ICD-10) - Calculus of kidney and ureter

N20.0 (ICD-10) - calculus of kidney

596 (ICD-9) - Other disorders of bladder

596.54 (ICD-9) - neurogenic bladder NOS

N31 (ICD-10) - Neuromuscular dysfunction of bladder, NEC

N31.9 (ICD-10) - neuromuscular dysfunction of bladder unspecified

788.99 (ICD-9) - Other symptoms involving urinary system

R39 (ICD-10) - other and unspecified symptoms and signs involving the genitourinary system

R39.9 (ICD-10) - Unspecified symptoms and signs involving the genitourinary system

599.70 (ICD-9) - Hematuria, unspecified

R31 (ICD-10) – Hematuria

R31.9 (ICD-10) - Hematuria, unspecified

753 (ICD-9) - congenital anomalies of urinary system

753.8 (ICD-9) - other specified congenital malformations of urinary system

Q64 (ICD-10) - other congenital malformations of urinary system

(x) Missing or Additional Fingers or Toes

Q 69.1 (ICD-10) - accessory thumb(s)

Q 69.2 (ICD-10) - accessory toes

755.10 (ICD 9) - syndactyly of multiple and unspecified sites

Q70 (ICD-10) – syndactyly

Q70.4 (ICD-10) – polysyndactyly, unspecified

Q70.9 (ICD-10) - syndactyly, unspecified

755.11 (ICD 9) - syndactyly of fingers without fusion of bone

Q70.10 (ICD-10) - webbed fingers, unspecified hand

Q70.11 (ICD-10) - webbed fingers, right Hand

Q70.12 (ICD-10) - webbed fingers, left hand

Q70.13 (ICD-10) - webbed fingers, bilateral

755.12 (ICD-9) - syndactyly of fingers with fusion of bone

Q70.00 (ICD-10) - fused fingers, unspecified hand

Q70.01 (ICD-10) - fused fingers, right hand

Q70.02 (ICD-10) - fused fingers, left hand

Q70.03 (ICD-10) - fused fingers, bilateral

755.13 (ICD-9) - syndactyly of toes without fusion of bone

755.14 (ICD-9) - syndactyly of toes with fusion of bone

Q 70.30 (ICD-10) - webbed toes, unspecified foot
755.20 (ICD-9) - Unspecified reduction to deformity of upper limb, congenital
Q71 (ICD-10) - reduction defects of upper limb
Q71.819 (ICD-10) - congenital shortening of unspecified upper limb
Q71.899 (ICD-10) - other reduction defects of unspecified upper limb
Q71.90 (ICD-10) - unspecified reduction defect of unspecified upper limb
755.30 (ICD-9) - unspecified reduction deformity of lower limb, congenital
755.4 (ICD-9) - congenital reduction deformities unspecified limb
Q72 (ICD-10) reduction in defects of lower limb
Q72.819 (ICD-10) - congenital shortening of unspecified lower limb
Q72.899 (ICD 10) - other reduction defects of unspecified lower limb
Q73 (ICD 10) - reduction defects of unspecified limb
755.50 (ICD 9) - unspecified anomaly of upper limb congenital
Q74 (ICD-10) - other congenital malformations of limb(s)
Q74.9 (ICD-10) - unspecified congenital malformation of limb(s)
Q74.8 (ICD-10) - other specified congenital malformations of limb(s)
755.60 (ICD-9) - unspecified congenital anomaly of lower limb
Q74.2 (ICD-10) - unspecified congenital malformation of lower limb(s) including pelvis girdle
755.67 (ICD-9) - congenital anomalies of foot not elsewhere classified
755.8 (ICD-9) - other specified congenital anomalies of unspecified limb
755.9 (ICD-9) - unspecified congenital anomaly of unspecified limb
728.9 (ICD-9) - unspecified disorder of muscle ligaments and fascia

(xi) Respiratory problems/Asthma

P28.81 (ICD10) - respiratory arrest of the newborn
770.4 (ICD 9) - primary atelectasis of newborn
P28.0 (ICD-10) - primary atelectasis of newborn
770.5 (ICD-9) - other and unspecified atelectasis of newborn
P28.19 (ICD-10) - other atelectasis of newborn
770.81 (ICD-9) - primary apnea of newborn
770.82 (ICD-9) - other apnea of newborn

P28.4 (ICD-10) - other apnea of newborn
771.81 (ICD-9) - septicemia (sepsis) of newborn
771.83 (ICD-9) - bacteremia of newborn
R78.81 (ICD-10) - bacteremia
P36.8 (ICD-10) - Other bacterial sepsis of newborn
P36.9 (ICD-10) - bacterial sepsis of newborn, unspecified
775.6 (ICD-9) - neonatal hypoglycemia
P70.4 (ICD-10) - other neonatal hypoglycemia
775.7 (ICD-9) - late metabolic acidosis of newborn
P74.0 (ICD-10) - late metabolic acidosis of newborn
775.81 ICD-9 other acidosis of newborn
P84 (ICD-10) - other problems of newborn
480 (ICD-9) - viral pneumonia
480.1 (ICD-9) - pneumonia due to respiratory syncytial virus
J12.1 (ICD 10) - respiratory syncytial virus pneumonia
466 (ICD-9) - acute bronchitis and bronchiolitis
466.0 (ICD-9) - acute bronchitis
J20 (ICD-10) - acute bronchitis
J20.9 (ICD-10) - acute bronchitis, unspecified
466.19 (ICD-9) - acute bronchiolitis, due to other specified organisms
J21 (ICD-10) - acute bronchiolitis
J21.8 (ICD-10) - acute bronchiolitis, due to other specified organisms
464 (ICD-9) - acute laryngitis and tracheitis
464.01 (ICD-9) - acute laryngitis with obstruction
464.4 (ICD-9) - croup
J05 (ICD-10) - acute obstructive laryngitis (croup) and epiglottitis
J05.0 (ICD-10) - laryngitis, acute obstructive (croup)
460 (ICD-9) - acute nasopharyngitis (common cold)
J00 (ICD-10) - acute nasal pharyngitis; also the code used for rhinitis, infective (common cold)
461 (ICD-9) - acute sinusitis

461.9 (ICD-9) - acute sinusitis, unspecified

J01 (ICD-10) - acute sinusitis

J01.90 (ICD-10) - acute sinusitis; Acute sinusitis, unspecified

J01.91 (ICD-10) - acute recurrent sinusitis, unspecified

J01.80 (ICD-10) - other acute sinusitis; Other acute sinusitis

J01.81 (ICD-10) - other acute recurrent sinusitis

462 (ICD-9) - acute pharyngitis; acute pharyngitis

J02 (ICD-10) - acute pharyngitis

J02.9 (ICD-10) - acute pharyngitis; Acute pharyngitis, unspecified

463 (ICD-9) - acute tonsillitis; Acute tonsillitis

J03 (ICD-10) - acute tonsillitis

J03.81 (ICD-10) - acute tonsillitis acute recurrent tonsillitis due to other specified organisms

J03.91 (ICD-10) - acute recurrent tonsillitis, unspecified

465 (ICD-9) - acute upper respiratory infections of multiple or unspecified sites

465.8 (ICD-9) - acute upper respiratory infections of multiple sites

465.9 (ICD-9) - acute upper respiratory infections of unspecified site

J06 (ICD-10) - acute upper respiratory infections of multiple and unspecified sites

J06.9 (ICD-10) - acute upper respiratory infection, unspecified

786 (ICD-9) - symptoms Involving respiratory system and other chest symptoms

786.2 (ICD-9) - cough

R05 (ICD-10) - cough; cough

786.05 (ICD-9) - shortness of breath

R06.02 (ICD-10) - shortness of breath

786.7 (ICD-9) - abnormal chest sounds

786.07 (ICD-9) - wheezing

R06.2 (ICD-10) - wheezing

786.04 (ICD-9) - Cheyne-Stokes respirations

R06.3 (ICD-10) - periodic breathing

478.19 (ICD-9) - other diseases of nasal cavity and sinuses

R09.2 (ICD-10) - respiratory arrest

784.91 (ICD-9) - post nasal drip
R09.82 (ICD-10) - post nasal drip
491 (ICD-9) - chronic bronchitis
491.22 (ICD-9) - obstructive chronic bronchitis with acute bronchitis
493.21 (ICD-9) - chronic obstructive asthma with Status asthmaticus
J44.0 (ICD-10) - acute bronchitis with chronic obstructive asthma; chronic obstructive pulmonary disease with (acute) lower respiratory infection
J45.909 (ICD-10) - allergic bronchitis NOS, unspecified asthma, uncomplicated
491.9 (ICD-9) - unspecified chronic bronchitis
J42 (ICD-10) - chronic bronchitis NOS; Unspecified chronic bronchitis
491.0 (ICD-9) - simple chronic bronchitis
J41 (ICD-10) - simple and mucopurulent chronic bronchitis
J41.0 (ICD-10) - simple chronic bronchitis
477 (ICD-9) - allergic rhinitis
477.8 (ICD-9) - allergic rhinitis due to other allergen
J30 (ICD-10) - vasomotor and allergic rhinitis
J30.89 (ICD-10) - other allergic rhinitis
472 (ICD-9) - chronic pharyngitis and nasal pharyngitis
472.0 (ICD-9) - chronic rhinitis
J31 (ICD-10) - chronic rhinitis, nasal pharyngitis, and pharyngitis
J 31.0 (ICD-10) - rhinitis, chronic
472.2 (ICD-9) - chronic nasal pharyngitis
J31.1 (ICD-10) - chronic nasal pharyngitis
J34.3 (ICD-10) - hypertrophy of nasal turbinates
J34.89 ICD-10 other specified disorders of nose and nasal sinuses
790.8 (ICD-9) - unspecified viremia
B34.9 (ICD-10) - viral infection, unspecified
J22 (ICD-10) - unspecified acute lower respiratory infection
J12 (ICD-10) - viral pneumonia NEC
J12.89 (ICD-9) - other viral ammonia

(xii) Serious Vision Problems

369 (ICD-9) - blindness and low vision

H54 (ICD-10) - Blindness and low vision

367 (ICD-9) - disorders of refraction and accommodation

367.20 (ICD-9) - astigmatism unspecified

H52 ICD-10 disorders of refraction and accommodation

H52.209 (ICD-10) - unspecified astigmatism, unspecified eye

367 (ICD-9) - hypermetropia

H52.03 (ICD-10) - hypermetropia, bilateral

367.1 (ICD-9) - myopia

H52.13 (ICD-10) - myopia, bilateral

362 ICD-9 other retinal disorders

362.22 (ICD-9) - retinopathy of prematurity stage 0

362.23 (ICD-9) - retinopathy of prematurity stage 1

362.24 (ICD-9) - retinopathy of prematurity stage 2

362.25 (ICD-9) - retinopathy of prematurity stage 3

362.26 (ICD-9) - retinopathy of prematurity stage 4

362.27 (ICD-9) - retinopathy of prematurity stage 5

H35 (ICD-10) - other retinal disorders

H35.119 (ICD-10) - retinopathy of prematurity stage 0 unspecified eye

H35.129 (ICD-10) - Retinopathy of prematurity stage 1 unspecified eye

H35.139 (ICD-10) - retinopathy of prematurity stage 2 unspecified eye

H35.149 (ICD-10) - retinopathy of prematurity stage 3 unspecified eye

H35.159 (ICD-10) - retinopathy of prematurity stage 4 unspecified eye

H35.169 (ICD-10) - retinopathy of prematurity stage 5 unspecified eye

369.4 (ICD-9) - legal blindness, as defined in U.S.A.

H54.8 (ICD-10) - legal blindness, as defined in U.S.A.

743.30 (ICD-9) - congenital cataract unspecified

Q12 (ICD-10) - congenital lens malformation

Q12.0 (ICD-10) - congenital cataract

(xiii) Skin Conditions

B37.2 (ICD-10) - Candidiasis of skin and nail

112.3 (ICD-9) - Candidiasis of skin and nails

P83.1 (ICD-10) - Neonatal erythema toxicum

(xiv) Spina Bifida

NONE

(xv) Unexplained and unresolved acid reflux (unresponsive to medication)

K30 (ICD-10) - functional dyspepsia (indigestion)

789.7 (ICD-9) - colic

R10.83 (ICD-10) - colic

789.07 (ICD-9) - abdominal pain generalized

R10.84 (ICD-10) - colic; Generalized abdominal pain

(xvi) Difficulty swallowing, breastfeeding or bottle-feeding

307.53 (ICD-9) - rumination disorder of infancy

F98.21 (ICD-10) - rumination disorder of infancy

787.02 (ICD-9) - nausea alone

R11.0 (ICD-10) - nausea

R11.10 (ICD-10) - vomiting; Vomiting, unspecified (>28 days old)

R11.12 (ICD-10) - projectile vomiting (>28 days old)

787.04 (ICD-9) - bilious emesis

R11.14 (ICD-10) - bilious vomiting (>28 days old)

774.2 (ICD-9) - neonatal jaundice associated with preterm delivery

P59.0 (ICD-10) - neonatal jaundice associated with preterm delivery

774.30 (ICD-9) - neonatal jaundice due to delayed conjugation cause unspecified

774.31 (ICD-9) - neonatal jaundice due to delayed conjugation in disease classified elsewhere

774.4 (ICD-9) - prenatal jaundice due to hepatocellular damage

P59.20 (ICD-10) - neonatal jaundice from unspecified hepatocellular damage

774.6 (ICD-9) - unspecified fetal and neonatal jaundice

P59.9 (ICD-10) - neonatal jaundice, unspecified

750.0 (ICD-9) - tongue tie

750.10 (ICD-9) - congenital anomaly of tongue unspecified

Q38.0 (ICD-10) - congenital malformation of lips NEC

Q38.1 (ICD-10) - ankyloglossia

Q38.3 (ICD-10) - other congenital malformations of tongue

V85.52 (ICD-9) - body mass index pediatric, 5th percentile to less than 85th percentile for age

Z68.52 (ICD-10) - body mass index pediatric, 5th percentile to less than 85th percentile for age

112.0 (ICD-9) - candidiasis of mouth

B37.0 (ICD-10) - candidal stomatitis

771.17 (ICD-9) - neonatal candida infection

P37.5 (ICD-10) - neonatal candidiasis

(xvii) Delay or inability to walk

R26.1 (ICD-10) - paralytic gait

781.0 (ICD-9) - abnormal involuntary movements

R25.1 (ICD-10) - tremor, unspecified

R25.2 (ICD-10) - cramp and spasm

781.3 (ICD-9) - lack of coordination

781.4 (ICD-9) - transient paralysis of limb

R27.8 (ICD-10) - other lack of coordination

(xviii) Depression

296 (ICD-9) - affective psychosis

296.00 (ICD-9) - manic affective disorder single episode unspecified degree

F30 (ICD-10) - manic episode

F30.1 (ICD-10) - manic episode with psychotic symptoms

F30.10 (ICD-10) - manic episode without psychotic symptoms unspecified

296.81 (ICD-9) - atypical manic disorder

F30.8 (ICD-10) - other manic episodes

F30.9 (ICD-10) - manic episode, unspecified

296.40 (ICD-9) - bipolar affective disorder manic, unspecified degree

F31 (ICD-10) - bipolar disorder

F31.0 (ICD-10) - bipolar disorder, current episode hypomanic

F31.10 (ICD-10) - bipolar disorder, current episode manic without psychotic features, unspecified

F31.3 (ICD-10) - bipolar disorder, current episode depressed, mild or moderate severity

296.99 (ICD-9) - other specified affective psychosis

307.40 (ICD-9) - nonorganic sleep disorder unspecified

307.41 (ICD-9) - transient order of initiating or maintaining sleep

307.42 (ICD-9) - persistent disorder of initiating or maintaining sleep

307.45 (ICD-9) - circadian rhythm sleep disorder of nonorganic origin

307.47 (ICD-9) - other dysfunctions of sleep stages or arousal

307.48 (ICD-9) - repetitive intrusions of sleep

307.49 (ICD-9) - other specific disorders of sleep of nonorganic origin

F51.01 (ICD-10) - primary insomnia

F51.02 (ICD-10) - adjustment insomnia

F51.03 (ICD-10) - paradoxical insomnia

F51.19 (ICD-10) - other hypersomnia not due to substance or known psychological condition

F51.3 (ICD-10) - somnambulism [sleepwalking]

F51.4 (ICD-10) - sleep terrors [night terrors]

F51.8 (ICD-10) - other sleep disorders not due to a substance or known physiological condition

307.50 (ICD-9) - eating disorder unspecified

F50 (ICD-10) - eating disorders

F50.9 (ICD-10) - eating disorder unspecified

309 (ICD-9) - adjustment reaction

309.9 (ICD-9) - unspecified adjustment reaction

F43 (ICD-10) - reaction to severe stress and adjustment disorders

F43.20 (ICD-10) - adjustment disorder unspecified

F43.21 (ICD-10) - adjustment disorder with depressed mood

F43.9 (ICD-10) - reaction to severe stress, unspecified

F43.25 (ICD-10) - adjustment disorder with mixed disturbance of emotions and conduct

309.4 (ICD-9) - adjustment disorder with mixed disturbance of emotions and conduct

(xix) Diagnosed lack of ability to function independently

V62.89 (ICD-9) - other psychological or physical stress NEC

Z73.9 (ICD-10) - other problems related to life management difficulty

Z73.6 (ICD-10) - limitation of activities due to disability

R41.83 (ICD-10) - borderline intellectual functioning

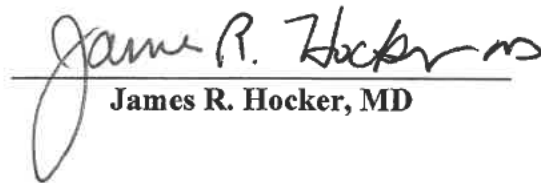
F. **SHOULD THE NCAM AND THE SCIENTIFIC STUDIES CATALOGUED IN EXHIBIT C HEREIN BE SHARED WITH ALL COUNSEL REPRESENTING NAS CLAIMANTS?**

In my expert opinion, in order to provide a level playing field to all NAS Counsel and all pro se NAS Claimants, in their submission and PI Trustee grading of NAS claims, I believe that the NCAM and the scientific studies cataloged in Exhibit C herein, **SHOULD BE** shared with all Counsel for NAS Claimants, and with all pro se Claimants. Otherwise, the NAS Counsel Leadership who created the NCAM may have an unfair competitive advantage in getting their NAS Claimants qualified. This process will also facilitate the “second chance” process I describe in paragraph A-2 for Claimants with possibly unsubstantiated exposure to opioids or unsubstantiated opioid-related damages.

I declare under penalty of perjury that the foregoing is true and correct.

EXECUTED, this 2 day of June, 2022.

FURTHER AFFIANT SAYETH NOT

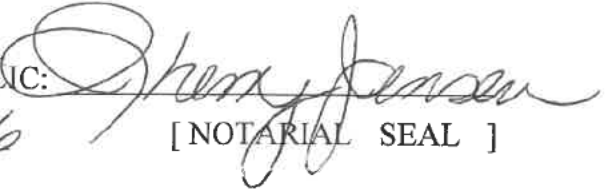

James R. Hocker, MD

STATE OF North Dakota
COUNTY OF Cass

BEFORE ME, the undersigned, personally appeared James R. Hocker, MD, and acknowledges that he signed the foregoing Affidavit, and that said Affidavit is true and correct to his knowledge and belief.

SWORN TO AND SUBSCRIBED before me this 2nd day of June, 2022.

Page -44-
NOTARY PUBLIC:



My Commission Expires:

June 14, 2026

[NOTARIAL SEAL]

SHERRY JENSEN
Notary Public
State of North Dakota
My Commission Expires June 14, 2026

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

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

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)

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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)

Attachment D

Dr. Hocker's Imprimatur Approving C

Chris Anderson

From: Edgar C. Gentle III
Sent: Thursday, July 14, 2022 6:01 AM
To: Chris Anderson
Subject: Fwd: Document review

Print

Sent from my iPhone

Begin forwarded message:

From: Jim Hocker
Date: July 14, 2022 at 5:03:40 AM CDT
To: "Edgar C. Gentle III"
Cc: Chris Smith
Subject: Re: Document review

Ed and Chris,

I think the manual looks great; very comprehensive; nobody deserving compensation should be missed. I agree with Ms. Trucks 2 suggestions. Konopin is a benzodiazepine.

Let me know if I can be of further service.

All the best,

Jim

On Jul 12, 2022, at 7:44 AM, Edgar C. Gentle III <[redacted]> wrote:

Good morning.

Yes sir!!!

Thanks Dr. Hocker!

Ed

Sent from my iPhone

On Jul 12, 2022, at 6:21 AM, Jim Hocker <[redacted]> wrote:

Good morning,

I am preparing for a deposition that is scheduled for tomorrow morning. I will get the document reviewed and back to you by Wednesday PM or Thursday morning. Does that work for you?

Thanks.

Jim

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