

# Chiari I Malformation CDE Revision History Document

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# Chiari I Malformation CDE Revision History Document

## January 2020 Revisions

- General Core CRF updated to replace 'Gender' question with 'Sex assigned at birth' and 'Gender identity'.
- Two new CDEs added to CRF: C58676 (Sex assigned at birth) and C58677 (Gender identity). C00035 has been removed
- Start-Up document updated to reflect these changes.

## May 2018 Revisions

- The CM Imaging case report form (F2507) was updated to reflect the following changes:
  - **Question 6:** Changed from Length of Syrinx TO Length of hydrosyringomyelia  
Definition - the minimal value of this field when fluid is present in the spinal cord (i.e. #6 is yes) is set to "1." A "segment" is defined as equal to or greater than the half the height of the corpus of the adjoining vertebral bodies at the mid-sagittal plane. Example: hydrosyringomyelia extending from just caudal to the mid-point of the C3 vertebral body to just rostral to the mid-point of the C5 vertebral body would be assigned a value of "2."]
  - **Question 9:** Maximum width of syrinx was changed TO Maximum width of hydrosyringomyelia  
9a. Added question - Greatest transverse diameter of the spinal cord  
9b. Added question - Greatest transverse diameter of the thecal sac
  - **Question 20:** Supraoccipital Length - Supraoccipital Length definition was revised to identify the internal peak where tentorium inserts internally, which is more relevant for Chiari. Supraoccipital Length, Figure 12, was revised to extended to the most posterior margin of the external occipital protuberance on midsagittal image.

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- **Question 28:** Spinal Dysraphism ADDED (excluding spina bifida occulta)
- **Question 31:** ADDED question - Empty sella turcica present?  
 Definition - Pituitary height:
  - o I: normal appearance—the superior aspect of the pituitary gland was either convex or flat
  - o II: mild (loss of pituitary height  $h > 2/3$  of the sella height H)
  - o III: moderate ( $1/3 H < h < 2/3 H$ )
  - o IV: severe ( $h < 1/3 H$ )
  - o V: empty sella if the sella turcica was enlarged and no pituitary parenchyma was observable

(where h denotes the pituitary height and H denotes the height of the sella turcica. Define h as the minimal pituitary height in the mid-sagittal plane  
 Define H as either the maximal depth of the sella turcica in the mid-sagittal plane as measured to the tuberculum sellae OR to the limbus sphenoidale- the latter may be favored due to ease of identification)

  - o Pituitary dorsal contour:  
 Convex, Flat, Concave (as viewed from above)
- The following changes were made to the Chiari I Malformation Start-Up and Highlight Summary document

Domain; Sub-Domain	Data Element	CDE ID	Old Classification	New Classification
Disease/Injury Related Events; Classification	Subject ID	C19247	Core	Supplemental
Disease/Injury Related Events; Classification	Injury date time	C05400	Core	Supplemental

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Outcomes and End Points; Assessing Comorbidities	Skin abnormality peizogenic papule indicator	C22411	Core	Exploratory
Outcomes and End Points; Assessing Comorbidities	Hydrocephalus family history slit ventricle indicator	C22449	Core	Supplemental
Outcomes and End Points; Assessing Comorbidities	Gravida maternal value	C11065	Core	Supplemental
Outcomes and End Points; Assessing Comorbidities	Pregnancy miscarriage medical termination still birth count	C22456	Core	Supplemental
Outcomes and End Points; Assessing Comorbidities	Parity maternal value	C11063	Core	Supplemental
Outcomes and End Points; Assessing Comorbidities	Medical history Menieres disease indicator	C22459	Core	Supplemental
Outcomes and End Points; Assessing Comorbidities	Medical history cervical radiculopathy disc disease indicator	C22465	Core	Supplemental
Outcomes and End Points; Assessing Comorbidities	Medical history sarcoidosis condition indicator	C22467	Core	Exploratory
Outcomes and End Points; Assessing Comorbidities	Medical history tuberculosis condition indicator	C22469	Core	Exploratory
Outcomes and End Points; Assessing Comorbidities	Medical history Lyme disease indicator	C21870	Core	Supplemental
Outcomes and End Points; Assessing Comorbidities	Medical history spinal stenosis indicator	C22475	Core	Supplemental
Outcomes and End Points; Assessing Comorbidities	Psychiatric anxiety indicator	C19831	Core	Supplemental
Outcomes and End Points; Assessing Comorbidities	Attention deficit hyperactivity disorder indicator	C22478	Core	Supplemental
Participant History and Family History; General Health History	Chiari malformation screening hypermobility family indicator	C21761	Supplemental-Highly Recommended	Supplemental
Participant History and Family History; General Health History	Chiari malformation screening echocardiogram mitral valve prolapse aortic aneurysm diagnosis indicator	C21766	Supplemental-Highly Recommended	Supplemental
Participant History and Family History; General Health History	Chiari malformation screening orthopedic joint hip dislocation unusual pain screen indicator	C21767	Supplemental-Highly Recommended	Supplemental
Disease/Injury Related Events; Classification	Chiari I malformation headache pressure daily occurrence indicator	C21690	Supplemental-Highly Recommended	Supplemental

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Disease/Injury Related Events; Classification	Chiari I malformation neck pain stiff radiate shoulder symptom indicator	C21691	Supplemental-Highly Recommended	Exploratory
Disease/Injury Related Events; Classification	Chiari I malformation prickle tingle numb arm leg frequent occurrence symptom indicator	C21692	Supplemental-Highly Recommended	Supplemental
Disease/Injury Related Events; Classification	Chiari I malformation position change dizzy symptom indicator	C21693	Supplemental-Highly Recommended	Supplemental
Disease/Injury Related Events; Classification	Chiari I malformation unsteady stand walk symptom indicator	C21694	Supplemental-Highly Recommended	Exploratory
Disease/Injury Related Events; Classification	Chiari I malformation headache pressure eye ear light sensitive symptom indicator	C21695	Supplemental-Highly Recommended	Exploratory
Disease/Injury Related Events; Classification	Chiari I malformation chronic fatigue short-term memory loss irritable symptom indicator	C21697	Supplemental-Highly Recommended	Exploratory
Disease/Injury Related Events; Classification	Chiari I malformation generalize weakness stiff arm leg symptom indicator	C21698	Supplemental-Highly Recommended	Exploratory
Disease/Injury Related Events; Classification	Chiari I malformation shortness breath blur vision ring ear urinary urgency heart palpitation symptom indicator	C21699	Supplemental-Highly Recommended	Exploratory
Disease/Injury Related Events; History of Disease/Injury Event	Headache primary anatomic site	C21778	Supplemental-Highly Recommended	Exploratory
Disease/Injury Related Events; History of Disease/Injury Event	Headache primary laterality anatomic site	C21780	Supplemental-Highly Recommended	Exploratory
Disease/Injury Related Events; History of Disease/Injury Event	Headache primary laterality anatomic site score	C21782	Supplemental-Highly Recommended	Exploratory
Disease/Injury Related Events; History of Disease/Injury Event	Headache frequency type	C21790	Supplemental-Highly Recommended	Exploratory
Disease/Injury Related Events; History of Disease/Injury Event	Headache frequency score	C21791	Supplemental-Highly Recommended	Exploratory
Disease/Injury Related Events; History of Disease/Injury Event	Headache duration type	C21837	Supplemental-Highly Recommended	Exploratory
Disease/Injury Related Events; History of Disease/Injury Event	Headache duration score	C21838	Supplemental-Highly Recommended	Exploratory
Disease/Injury Related Events; History of Disease/Injury Event	Headache aggravating pain factor type	C21842	Supplemental-Highly Recommended	Exploratory

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Disease/Injury Related Events; History of Disease/Injury Event	Headache aggravating pain factor score	C21843	Supplemental-Highly Recommended	Exploratory
Disease/Injury Related Events; History of Disease/Injury Event	Headache assessment total score	C21844	Supplemental-Highly Recommended	Exploratory
Treatment/Intervention Data; Drugs	Medication prior name	C18035	Supplemental-Highly Recommended	Supplemental
Treatment/Intervention Data; Drugs	Medication prior or concomitant dose	C02006	Supplemental-Highly Recommended	Supplemental
Treatment/Intervention Data; Drugs	Medication prior or concomitant dose frequency	C02011	Supplemental-Highly Recommended	Supplemental
Treatment/Intervention Data; Drugs	Medication prior or concomitant start date and time	C02016	Supplemental-Highly Recommended	Supplemental
Treatment/Intervention Data; Drugs	Medication prior or concomitant end date and time	C02008	Supplemental-Highly Recommended	Supplemental

### November 2017 Revisions

- The CM Start-Up document was missing twelve CDEs. Addition of the following CDEs were added to the document:

C13758	<a href="#">Imaging diagnosis stroke transient ischemic attack indicator</a>	Indicator of the diagnosis of stroke/transient ischemic attack (TIA) for imaging positive	Supplemental-Highly Recommended
C21872	<a href="#">Medical history visual impairment indicator</a>	The indicator related to personal medical history of visual impairment or legally blind.	Supplemental-Highly Recommended

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C21873	<a href="#">Medical history hearing deficit indicator</a>	The indicator related to personal medical history of hearing deficit or use of hearing aid.	Supplemental–Highly Recommended
C21874	<a href="#">Medical history paraplegia quadriplegia indicator</a>	The indicator related to personal medical history of paraplegia/quadruplegia.	Supplemental–Highly Recommended
C21882	<a href="#">Surgical history cataract removal indicator</a>	The indicator related to surgical history of cataract removal.	Supplemental–Highly Recommended
C21884	<a href="#">Pain lower back indicator</a>	The indicator relating to lower back pain.	Supplemental–Highly Recommended
C21885	<a href="#">Pain general leg indicator</a>	The indicator relating to general leg pain.	Supplemental–Highly Recommended
C21886	<a href="#">Injury Head Indicator</a>	The indicator relating to traumatic head injury.	Supplemental–Highly Recommended
C21887	<a href="#">Injury whiplash indicator</a>	The indicator relating to injury in the form of whiplash.	Supplemental–Highly Recommended
C21888	<a href="#">Injury fall head neck indicator</a>	The indicator relating to injury in the form of the patient falling on their head or neck.	Supplemental–Highly Recommended
C21689	<a href="#">Beighton Score - Total score</a>	Total score as related to the Beighton Score	Supplemental–Highly Recommended
C12875	<a href="#">Echocardiogram mitral valve</a>	Assessment with echocardiography of the absence or presence of prolapse of the mitral valve, often with regurgitation, associated with	Supplemental–Highly Recommended

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	<a href="#">prolapse indicator</a>	myxomatous proliferation of the leaflets of the mitral valve.	
C22433	<a href="#">Medical history aortic root enlargement indicator</a>	The indicator related to any medical history of the enlargement of the subject's aortic root.	Supplemental–Highly Recommended
C22402	<a href="#">Hereditary disorder connective tissue diagnosis indicator</a>	The indicator related to personal or family history of double jointedness or excessive joint flexibility or dislocations, also known as Hereditary Disorder of Connective Tissue (HDCT).	Supplemental–Highly Recommended
C22776	<a href="#">Hereditary disorder type</a>	The type related to hereditary disorder of connective tissues.	Supplemental–Highly Recommended
C22775	<a href="#">Hereditary connective tissue disorder diagnosis type</a>	The type related to hereditary disorder of connective tissues.	Supplemental–Highly Recommended