

Pediatric Heart Network: Single Ventricle Reconstruction Trial

Code List M: Complications

CODE	COMPLICATION
	<b>Cardiac General</b>
	Arrhythmia (only record if requires medication or treatment)
M-0001	Atrial fibrillation
M-0002	Atrial flutter
M-0003	Supraventricular tachycardia
M-0004	Junctional ectopic tachycardia
M-0005	Sinus node dysfunction (requiring pacing)
M-0006	Atrioventricular block (second or third, not first)
M-0007	Ventricular tachycardia
M-0008	Ventricular fibrillation
	<b>Mediastinum</b>
M-0020	Hemopericardium (requiring intervention, includes post-op mediastinal hemorrhage, N.B. hemorrhage requiring restenotomy = SAE)
M-0021	Pericardial effusion (requiring drainage)
M-0022	Post-pericardiotomy syndrome (requiring treatment)
	<b>Cardiac Performance</b>
M-0030	Hypotension (<40 mmHg for neonates; < 50 mm Hg after Stage II)
M-0031	Hypertension (requiring chronic [>30d] post-discharge therapy, therapy should be at therapeutic doses and specifically prescribed for the treatment of hypertension)
M-0032	RV dysfunction- (requiring escalation or initiation of therapy, not to include immediate post-op dysfunction routinely associated with CPB)
	<b>Valves</b>
M-0033	Semi-lunar valve insufficiency or stenosis (requiring treatment initiation or escalation)
M-0034	Atrioventricular valve insufficiency or stenosis (requiring treatment initiation or escalation)
M-0035	Prosthetic valve dysfunction
	<b>Great Vessels</b>
M-0036	SVC stenosis (anatomic, symptomatic, "SVC syndrome")
M-0037	SVC occlusion
M-0038	IVC occlusion
M-0099	Other cardiovascular
	<b>Respiratory</b>
M-0101	Chronic respiratory failure (intubated for > 2 weeks after surgery)
M-0102	Chylothorax (Postoperative accumulation of chylous fluid in the pleural space requiring intervention whether by evacuation, dietary change and / or medical treatment)
M-0104	Hemothorax (requiring drainage)
M-0105	Phrenic nerve injury/ diaphragmatic paralysis (newly elevated diaphragm on CXR)
M-0106	Pleural effusion (requiring drainage >7 days post- op, other)
M-0107	Pneumothorax (requiring tube insertion)

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M-0108	Tracheal injury
M-0109	Vocal cord injury (direct visualization)
M-0110	Airway obstruction- requiring a significant intervention
M-0111	Hypoxia (requiring readmission or escalation of care)
M-0112	Acute respiratory distress (requiring initiation or escalation of therapy)
M-0113	Aspiration (radiological or bronchoscopic evidence)
M-0199	Other respiratory
	<b>Neurological</b>
M-0203	Choreoathetosis/posturing (moderate involuntary movements interfering with function)
M-0204	Coma
M-0205	Intracranial bleeding (confirmed by imaging)
M-0206	Seizure(s) - definite (EEG or obvious motor)
M-0207	Stroke (confirmed by imaging study)
M-0209	Hydrocephalus (report if CTCAE $\geq 2$ or higher)
M-0210	Neurological deficit persisting at discharge not attributed to any of above diagnoses
M-0299	Other neurological
	<b>Gastrointestinal</b>
M-0301	Direct bilirubin > 4
M-0303	Liver failure (AST, ALT or GGT >500)
M-0304	NEC, confirmed (pneumatosis or free air)
M-0305	NEC, suspected (NPO, antibiotics started)
M-0306	Other esophageal or bowel perforations not associated with NEC
M-0307	Upper GI bleed, requiring treatment
M-0309	Stricture/stenosis/GI (CTCAE $\geq$ grade 2)
M-0310	Dehydration (requiring IV fluids for >24 hrs)
M-0399	Other gastrointestinal
	<b>Infectious</b>
M-0401	Empyema
M-0402	Endocarditis
M-0414	Gastroenteritis or Enteritis
M-0408	Line infection, Bacterial (+ blood cultures)
M-0409	Line infection, Fungal (+ blood cultures)
M-0410	<del>Pneumonia</del> , Respiratory infection, Bacterial (Requiring the initiation of therapy)
M-0411	<del>Pneumonia</del> , Respiratory infection, Viral (Requiring the initiation of therapy)
M-0404	Mediastinitis/ Wound Infection, deep (requires I & D, sternal instability)
M-0407	Wound infection, superficial (erythema, possible tissue separation and drainage)
M-0405	Sepsis, confirmed (positive blood culture, not line infection)
M-0412	Sepsis, clinical with negative cultures
M-0413	Urinary tract infection
M-0499	Other infection
	<b>Renal</b>
M-0501	Acute renal failure (creatinine > 1.5 mg/dl (133 micromole/L) or tripling of baseline value for $\leq 7$ days) temporary dialysis
M-0502	Chronic renal failure (creatinine > 1.5 mg/dl (133 micromoles/L) or tripling of baseline

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	value for >7 days) chronic dialysis
M-0599	Other renal
	<b>Hematologic</b>
M-0601	Anemia (Hemoglobin < 10 gm/dl)
M-0602	Thrombocytopenia (platelets < 50,000)
M-0604	Hematoma (CTCAE grade $\geq 2$ )
M-0605	Hemorrhage, GI (CTCAE grade $\geq 2$ ) [heme + stools]
M-0606	Hemorrhage, GU (CTCAE grade $\geq 2$ )
M-0607	Hemorrhage, pulmonary/upper respiratory (CTCAE grade $\geq 2$ )
M-0699	Other hematologic
	<b>Vascular</b>
M-0603	Thrombus/thromboembolism
M-0799	Vascular, other
	<b>Other Complication</b>
M-9999	Other