

**Table S4: Examples of assigning conditions to different severity grades of hepatic impairment**

Term	Disease/lab parameter
Severe hepatic impairment	Liver cirrhosis, Child-Pugh-Score C
Severe hepatic impairment	Acute hepatitis
Severe hepatic impairment	Serum Albumin < 25 g/l
Severe hepatic impairment	Coma/Precoma hepaticum
Moderate hepatic impairment	Liver cirrhosis, Child-Pugh-Score B
Mild hepatic impairment	Liver cirrhosis, Child-Pugh-Score A

Further, often used combinations of terms in SmPCs/PI might be added to the list, when a consensus for severity is established. For example, 'active liver disease or unexplained persistent elevations of serum transaminases exceeding 3 times the upper limit of normal' could be used as a lab value (serum transaminases, > 3 × ULN) for defining 'active liver disease'. Still there is uncertainty to what conditions 'unexplained and persistent' includes.