

Bruise, Contusion and Ecchymosis MedDRA Proactivity Proposal Implementation MedDRA Version 16.0

I. MSSO Recognized Definitions of Concepts and Terms

The MSSO has designated *Dorland's Illustrated Medical Dictionary* as the standard reference for medical definitions. The following definitions are cited from Dorland's 27th edition:

Bruise – A superficial injury produced by impact without laceration; a contusion

Contusion – A bruise; an injury of a part without a break in the skin

Ecchymosis – A small hemorrhagic spot, larger than a petechia, in the skin or mucous membrane forming a nonelevated, rounded or irregular, blue or purplish patch.

Hematoma – A localized collection of blood, usually clotted, in an organ, space, or tissue, due to a break in the wall of a blood vessel.

Hemorrhage – The escape of blood from the vessels; bleeding.

Petechia – A pinpoint, non-raised, perfectly round, purplish red spot caused by intradermal or submucous hemorrhage.

Additional comments regarding the definitions:

- *Bruise* and *contusion* are synonymous, and are often used in a colloquial context.
- *Bruise* and *contusion* are each considered a result of injury.
- *Bruise* and *contusion* have been used to describe minor hemorrhage within tissue, where traumatized blood vessels leak blood into the interstitial space. Commonly, capillaries and sometimes venules are injured within skin, subcutaneous tissue, muscle, or bone.
- In addition to trauma, the terms *bruise*, *ecchymosis*, and to a lesser extent, *contusion*, have also been used as clinical signs of disorders of platelet function, coagulopathies, venous congestion, allergic reactions, etc.
- *Hemorrhage* may be used to describe blood escaping from vessels and retained in the interstitial space, and perhaps more commonly, to describe the escape of blood from vessels, and flowing freely external to the tissues.
- *Hematoma*, in practice, is usually used to describe a protuberant or mass-like confluent collection of blood within a tissue or space. It is less frequently used to describe the minor intra-tissue hemorrhage characteristic of a bruise, contusion, ecchymosis, petechia, etc. Of particular note, hematoma is not an element of the Dorland's definition of *bruise* or of *contusion*.

- The definition of *ecchymosis* does not state *per se* that the concept is associated with injury.

II. Review of Existing Term Placement in MedDRA v15.1 and Proposed Conventions Regarding Bruise, Contusion and Ecchymosis Concepts

On the basis of the respective subscribers' proactivity requests, and the relevant definitions from *Dorland's Illustrated Medical Dictionary*, an evaluation of the current and non-current terms which include "bruise," "contusion" and "ecchymosis," and their hierarchical status, was performed by the MSSO Medical Team.

The following general conventions were established from this review:

- Bruise terms are generally placed at the LLT level, and linked to an appropriate contusion PT, with the following exception:
 - Considering that "bruise" and "contusion" are synonyms, a specific *bruise* term may be at the PT level if it represents the common clinical use of the respective concept (e.g., PT *Increased tendency to bruise*, and PT *Application site bruising*).
- For those bruise LLTs that did not map to PT *Contusion*, a site-specific or procedure-specific contusion PT is proposed. (e.g., LLT *Penile bruise* would now map to new PT *Penile contusion*, instead of PT *Penile haematoma*). Since bruises/contusions are primarily a result of injury, or procedural complications, the respective primary SOC would appropriately be SOC *General disorders and administration site conditions*, or SOC *Injury, poisoning and procedural complications*.
- For contusion LLTs that did not map to PT *Contusion*, a site-specific or procedure-specific contusion PT is proposed, generally in manner as described for bruise LLTs.
- Because ecchymosis is a localized interstitial hemorrhage of usually a small quantity of blood, nonspecific ecchymosis LLTs will continue to be mapped to PT *Ecchymosis*, and site-specific LLT ecchymosis terms will continue to be mapped to site-specific or procedure-specific PT hemorrhage terms.