

## NHSBSA Dental Services

### In the spotlight

#### Article 2: Inlays and Onlays

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**What is an Inlay?:** Inlays are indirect restorations (made outside of the mouth) which restore lost tooth tissue and are a 'custom made device. They may be used to restore moderate to large amounts of tooth tissue destruction, where clinically a direct restoration is considered to be unsuitable. Alternative treatment options, including direct restorations should have been discussed with the patient. Tooth preparation by a dentist is required to remove undercut areas and to create features which prevent the inlay being dislodged from the tooth during mouth function.

The provision of an indirect restoration, including an inlay, for minimally sized cavity would be expected to be relatively rare and a direct alternative generally considered appropriate.

**Inlays with cuspal coverage:** An indirect restoration to restore lost tooth tissue which may include one or more lost tooth cusps. As with simple inlays, tooth preparation by a dentist is required to remove undercut areas and to create features which prevent the inlay being dislodged from the tooth during mouth function.

**What is an Onlay?:** Onlays are indirect restorations that replace lost tooth tissue but also extend across weakened parts of the tooth to protect these areas. The key feature of the onlay is the part which extends over the occluding (biting) surfaces of the tooth to facilitate this feature tooth preparation by a dentist may be required.

**What materials can inlays and onlays be made from?:** Under the current NHS Patient Charge Regulations 2005<sup>(1)</sup>, inlays and onlays can be made in alloys containing 60% or more fine gold, porcelain, composite resin and ceramics.

**Provision of inlays and onlays under NHS Regulations:** Under current NHS Patient Charge Regulations 2005, laboratory made inlays and onlays are a Band 3 item <sup>(1)</sup>. If clinical records were subsequently reviewed following submission of a claim including an inlay/onlay treatment item, then there would be an expectation

that the record would include justification for the provision of this indirect restoration including evidence of a discussion with the patient regarding any alternative treatment options, including direct restorations<sup>(2)</sup>.

Inlays or onlays fabricated at the chair-side using a special milling machine such as Cerec restorations are also considered a Band 3 item. Practices producing inlays/onlays using special milling machines must register with the Medical and Healthcare Products Authority (MHRA) and, as a 'Manufacturer' of dental appliances/custom made devices, must ensure that a statement of manufacture is available to the patient for whom the dental appliance is made as well as ensuring it meets with the definition of a custom made device which includes "...made in accordance with a duly qualified medical practitioner's written prescription" <sup>(2)</sup>.

### **Changes to medical devices regulations**

Custom made devices are subject to medical devices regulations. From 26 May 2020 the current Medical Devices Directive (MDD) will change to become the Medical Device Regulations (MDR).

The original framework for medical devices, which consisted of the Medical Devices Directive (MDD) 93/42/EEC and Active Implantable Medical Devices (AIMD) Directive 90/385/EEC, has been amended. These directives have now been combined under the MDR.

In the UK the MHRA is the competent authority responsible for the MDR. The new regulation changes entered into force 26 May 2017 and MDR fully applies from 25 May 2020. Devices that comply with the MDR regulation can be 'placed on the market' prior to 26 May 2020 by those manufacturers who are formally registered with the MHRA.

If you commission and manufacture dental appliances you must comply with the MDR. Compliance with this is a legal requirement and failure to comply is a criminal offence<sup>(3)</sup>

**Some good practice guidelines:** In addition to a full mouth examination as required for a Band 3 course of treatment, more specific assessment of particular teeth should be considered, and could include special investigations such as radiographs <sup>(4)</sup>; pulp testing and periodontal assessment. Before considering indirect restorations, it is expected that the dentist would have usually addressed any active dental disease first.

**Claiming an inlay or onlay on an FP17 Form?** - The number of teeth provided with inlays or onlays, (using an indirect technique and permanent material specified in the current Regulations<sup>(1)</sup>) should be indicated in **box E of Part 5A** of the FP17 Form. **Box K ('Other treatment') and Box 8 ('Crowns Provided') should not be used for the provision of inlays or onlays.**

#### References:

1. SI 2005 No. 3477 - The NHS (Dental Charges) Regulations 2005
2. NHS Dental Services 'Ask Us' Band 3 Inlay Claiming: - <https://faq.nhsbsa.nhs.uk/knowledgebase/category/?id=CAT-01011&parentid=>
3. <https://www.gdc-uk.org/search?querytext=Commissioning+and+Manufacturing+Dental+Appliances>
4. 'Selection Criteria for Dental Radiography, Good Practice Guidelines, Third edition; 2013', FGDP (UK) Updated February 2018; ISBN No: 978-1-9999761-0-1.