## A. Service Specifications

<table>
<thead>
<tr>
<th>Service Specification No:</th>
<th>170096S</th>
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<tbody>
<tr>
<td>Service</td>
<td>Small bowel transplantation service (adults)</td>
</tr>
<tr>
<td>Commissioner Lead</td>
<td>For local completion</td>
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<tr>
<td>Provider Lead</td>
<td>For local completion</td>
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</table>

### 1. Scope

#### 1.1 Prescribed Specialised Service

This service covers the provision of assessment, transplantation and lifelong follow up of adult patients requiring small bowel transplantation.

#### 1.2 Description

Small bowel transplantation services include services provided by Highly Specialist Small Bowel Transplant Centres. This applies to provision in adults.

#### 1.3 How the Service is Differentiated from Services Falling within the Responsibilities of Other Commissioners

NHS England commissions small bowel transplantation services for adults from Highly Specialist Bowel Transplant Centres.

Clinical Commissioning Groups (CCGs) do not commission any elements of this service.

Activity is identified via local data flows, which apply to Highly Specialist Small Bowel Transplant Centres only.

### 2. Care Pathway and Clinical Dependencies

#### 2.1 Care Pathway

Please note that access to treatment will be guided by any applicable NHS England national clinical commissioning policies.

This specification relates specifically to transplantation and in terms of this specification begins when the patient undergoes assessment for transplantation prior to joining the transplant list. The key components of the service are:
- pre-transplant assessment
- listing
The transplant pathway will be delivered by the specialist small bowel transplant centres. The infrastructure will include the necessary resources of staffing, beds, access to theatres, access to Histocompatibility and Immunogenetics (H&I) services and the interdependencies described in this specification. This must be supported by a multidisciplinary team (MDT) process and a robust clinical governance structure including clinical audit. Patients should have a nominated lead clinician to manage their care at each stage of the pathway.

The specialist MDT should include:
- a transplant surgeon with expertise in bowel related transplantation
- gastroenterologist / intestinal failure specialist
- anaesthesia / critical care
- specialist nurse / recipient co-ordinator

With the addition of extended MDT membership as necessary:
- hepatologist
- clinical psychologist
- diagnostic radiologist
- interventional radiologist
- transplant histopathologist
- microbiologist with an interest in the care of immunosuppressed patients
- dietitian
- pharmacist
- physiotherapist
- H&I scientist

**Assessment**
It is expected that timely investigation and written referral to the transplant team, together with appropriate information for the patient is provided during the transplant pathway. All patients will undergo a multidisciplinary transplant assessment prior to being put on the waiting list. Patients will be placed on, or moved off the waiting list after discussion with the MDT and the patient. The provider is required to copy all correspondence with patients and between consultants and the patient’s GP.

**Transplant listing**
When a patient has completed their assessment and is considered a suitable transplant candidate they will be entered onto the waiting list as soon as possible. This will be the responsibility of the recipient transplant co-ordinator (or other named person). Patients will be made aware of their activation status.

**Follow up care**
All transplant recipients require regular follow up post-operative care. Follow up must be patient focused and units should consider local shared care arrangements with blood tests and telephone follow up in addition to clinic visits.

The transplant centre remains responsible for all patient follow up care and changes in therapy. The management of the patient’s immunosuppression will be managed by the transplant centre. Services will have a co-located pharmacy. Subsequent follow up will be on a defined frequency (not less than
annually) and will depend on patient need. Routine follow up is intended to identify and manage any emerging problems relating to the transplant. Shared care may be initiated with the referrer.

The long term care of transplant recipients will include holistic assessment of the patient’s progress along with pre-emptive strategies to minimise future health, physical and psychological problems. This will include regular review of their immunosuppressive therapy which will be tailored to prolong the life of their transplant whilst minimising the risk of side effects. In addition, patients will have their risk of future cardiovascular, kidney and bone disease assessed with steps taken to minimise these risks. Patients will be made aware of their increased risk of malignancy and counselled about appropriate changes in their lifestyle. Post-transplant patients will be encouraged to attend cancer screening programmes if appropriate.

Provision for post-transplant human leukocyte antigens (HLA) specific antibody monitoring and investigation of humoral rejection episodes will be part of the transplant service. Acute humoral or antibody mediated rejection (AMR) is attributed to the presence of alloantibodies against the graft, which could be either antibodies against HLA - class I and / or II, non-HLA antigens or endothelial antigens. Diagnosis of AMR is made through the tissue biopsy and presence of antibodies i.e. donor-specific antibodies (DSA). In intestinal transplantation the histopathological changes are not well characterised and lack of sensitivity to immunostaining has led to diagnostic and treatment dilemmas of humoral rejection. The question of whether humoral rejection / antibody mediated rejection contributes to long term graft damage remains unanswered. Patients who have a failing transplant will be identified at an early stage as outlined in this specification to ensure that they are prepared for the next stage of treatment.

A consultant level healthcare professional will be available for every transplant clinic. Access to a dietician, pharmacist and clinical psychologist are essential. The routes to access social services and other support services will be offered to those patients requiring them.

**Transition**

Transition in health care is recognised as a developmentally mediated process which ensures optimal health and wellbeing outcomes for young people as they move, in partnership with their health care teams, towards and into adult services and lifestyles.

The transition pathway should enable young people (and their parents / carers) to become and remain active partners in their care, prepare for transfer(s) and engage with adult health services, through the provision of a transition process. This should be based on developmentally appropriate care planning which is introduced in the paediatric service and continued in adult services and described by a transition care pathway which has been co-designed by paediatric and adult services, young people and their parent / carers. This is shared with Primary Care to ensure GPs have the relevant information to support young people (and their parent / carers) during and after transition.

Patients will transition from paediatric to adult services between 16 and 18 years of age, when considered appropriate by the patient, family and clinical team. Transition from child to adult small bowel transplantation services will occur in a staged fashion, with the timing and pace to be tailored to the needs of each individual patient. Patients and families should have the opportunity to meet a clinician from the adult team in a supported manner prior to transfer.
ASSESSMENT

CRITERION: Referral to adult small bowel transplant provider from specialist centre (including intestinal failure, oncology, liver transplantation)

Assessment by transplant team with MDT discussion → Deterioration on list may lead to contraindication to transplant → Discussion between gastroenterology and transplant teams to agree management plan

LISTING FOR SMALL BOWEL TRANSPLANT

CRITERION: Eligible for small bowel transplant

Discussion at NASIT → Further intestinal rehabilitation before consideration for transplant

Decision to list for small bowel transplant

On active waiting list for small bowel transplant → Condition deteriorating such that transplant may be contraindicated → Not eligible for small bowel transplant. Discharged

SMALL BOWEL TRANSPLANT

CRITERION: Organ allocation and recipient is available and assessed as fit for surgery

Small bowel transplanted

Post-op recovery and graft support

FOLLOW UP

Shared Care: Transplant team to provide lifelong follow-up
2.2 Interdependence with Other Services

The pathway begins when the patient undergoes assessment for transplantation prior to being added to the waiting list. For this section the spell of care is defined at the inpatient episode for the actual transplant surgery. Optimum delivery of the agreed pathways requires effective working relationships with the following services and organisations, but not limited to:

Co-located services (need to be provided on the same site)
- Nephrology
- Intensive care
- Theatre and anaesthetic departments
- Radiology (including interventional radiology)
- Pharmacy
- Dietetics
- Allied health professionals (including physiotherapy)
- Histopathology

Interdependent services (needed during the spell of care)
- Gastroenterology
- Microbiology / infectious disease
- Blood transfusion
- Cardiology (cardiopulmonary assessment and investigations)
- H&I laboratory (accredited by Clinical Pathology Accreditation (CPA) / United Kingdom Accreditation (UKAS))

Related services (preceding or following the spell of care)
- Paediatric Small Bowel transplantation centres
- Primary care
- Histopathology
- Haematology / oncology for management of patients with post-transplant lymphoproliferative disorders
- Clinical psychology
- NHS Blood and Transplant (NHS BT) – listing and allocation

Human Tissue Authority – regulatory approval; competent authority for the EU Organ Donation Directive on the Quality and Safety of Organs.

3. Population Covered and Population Needs

3.1 Population Covered By This Specification

This service specification covers the adult population within the commissioning responsibility of NHS England. Commissioning arrangements for the devolved nations in relation to this service are as set out in UK-wide Commissioning Arrangements of Highly Specialised Services published on the NHS England website.

The NHS England contract includes provision for the service to treat eligible patients from overseas under S2 and aligned referral arrangements. Providers are reimbursed for appropriately referred and recorded activity as part of this contract.
**Acceptance criteria**

The service will accept inward referrals from intestinal failure, gastroenterology, hepatology and other specialist services. The service will also accept referrals from other providers of small bowel transplantation, particularly when the referring service does not undertake the specific transplant the patient requires.

The service will accept referrals for all patients who are medically suitable regardless of gender, ethnicity, disability, faith or sexual orientation.

**Exclusions**

Absolute exclusion criteria for assessment are covered by the listing criteria for transplantation. Patients under the age of 18 are excluded from this service specification.

Trusts performing procedures on patients outside of S2 arrangements and aligned referral arrangements will need to continue to make the financial arrangements directly with the governments involved, separately from their contract with NHS England. Eligibility for organs is according to agreed DH guidelines.

### 3.2 Population Needs

The small bowel and multivisceral transplant service was established in the UK in the early 1990s. The number of transplants has fluctuated since the programme was established with up to 15 transplants usually carried out in adults each year. Most years there are fewer than 20 patients on the waiting list.

Intestinal transplantation has evolved into an established therapeutic modality in the management of patients with irreversible intestinal failure. It is performed in patients with short bowel syndrome, with multivisceral transplantation reserved for those patients who develop cholestatic liver disease from total parenteral nutrition. Primary indications for intestinal transplant include depletion of central venous access sites, multiple episodes of catheter related sepsis, electrolyte disturbance, dehydration, and progressive cholestatic liver failure. Additional indications for intestinal and multivisceral transplant include diffuse porto-mesenteric thrombosis, malignancies limited to the abdominal compartment, and congenital motility disorders of the intestine.

### 3.3 Expected Significant Future Demographic Changes

It is expected that the service will increase slowly in the future, with possibly activity growth linked to the expansion of intestinal failure services nationally and the inclusion of new indications for transplantation.

### 3.4 Evidence Base

When comparing survival data for home parenteral nutrition (HPN) and transplanted patients it is important to note that patients undergoing transplantation are a higher risk group. Many patients are assessed for transplantation because they have developed complications of HPN and those who have other indications often have extensive co-morbidity. Therefore there are no matched groups for comparison. Ideally a study would consider patients with and without transplantation who have no complications of HPN.

In the absence of such evidence from a controlled trial the best current evidence comes from a study carried out in 2004 by Pironi and colleagues who pooled data from Europe, to establish the number of patients who fulfilled USA guidelines for intestinal transplantation, and the outcome of these patients who did or did not undergo transplantation. 688 adult patients were identified in 5 European countries (including the UK). 16% of such patients were judged to be immediate or potential candidates for
intestinal transplantation. The study was limited by heterogeneous data across countries and small numbers (particularly of transplanted patients). Survival in the 10 patients receiving a first isolated small bowel transplant was 89%, compared with 85% in the candidates that fulfilled transplant criteria with parenteral nutrition failure but who did not receive transplants; the indications for transplantation in these cases were central venous catheter complications. In those patients whose indication for transplantation was that of parenteral nutrition-related liver failure, survival was 70%. Among the major contributing countries, candidacy ranged 0.3-0.8 / million population (for adults).

The information from the study above is helpful but not definitive when considering the likely demand and indications for transplantation in the UK, where the availability of intestinal failure services is different from other European countries and the USA. Indeed, North American transplant guidelines do not fully represent the decision-making during UK assessment for transplantation. Neither do these data allow for the changes that have taken place in the delivery of intestinal failure services and intestinal transplantation in the more than 10 years since the survey was carried out.

Small bowel transplantation is a highly specialised treatment for the management of irreversible intestinal failure. There are a number of primary conditions that result in intestinal failure and the treatment options available are limited. Initially the patients are supported with parenteral nutrition but complications secondary to this may result in the need to consider intestinal transplantation.

4. Outcomes and Applicable Quality Standards

4.1 Quality Statement – Aim of Service

A small bowel transplant may be considered for people with intestinal failure who develop complications from total parenteral nutrition (TPN). These complications include impending or overt liver failure, thrombosis of central veins, frequent central venous catheter infections or numerous episodes of severe dehydration. Intestinal failure is most often caused by short gut syndrome or a non-functioning bowel due to gastrointestinal motility disorders. Short gut syndrome can be caused by a number of conditions and processes including inflammatory bowel disease, volvulus and mesenteric vascular occlusion. Other indications may include slow-growing invasive tumours. Quality of life considerations may also play a part in the eligibility of individual patients for intestinal transplantation.

The aim of the service is to provide comprehensive care to patients who either may require or who have received a small bowel transplant. The service is commissioned to provide a comprehensive assessment, transplantation and follow up service to eligible patients who are fit enough to undergo the procedure. This service aims to improve the quality and length of life of patients undergoing the procedure, and to have outcome figures at least comparable to the best centres internationally.

There are four procedures performed as part of the intestinal transplant programme:

- intestine alone
- liver and intestine
- multivisceral (three or more abdominal organs, including liver, stomach, intestine and pancreas)
- modified multivisceral (two or more abdominal organs, including stomach, intestine and pancreas)

All patients receive an artificial opening of the bowel onto the abdominal wall called a stoma. This allows the transplant team to assess how the transplanted bowel is functioning and allows easy access for biopsies and also for endoscopic examination of the transplanted bowel. Sometimes the patient’s abdomen cannot be closed immediately and it may take several days to achieve closure. During this time the patient remains on the intensive care unit. Patients may require a variety of surgical
reconstructive techniques in order to achieve abdominal wall healing. In some patients, abdominal wall closure may be facilitated by the inclusion of a transplanted abdominal wall (a composite tissue graft) usually from the same donor as the intestine.

Providers of small bowel transplant services will ensure that as a minimum the following care is provided:

- Equity of access to transplantation regardless of point of referral and location
- Clear and unambiguous care pathways, supported by the provision of culturally appropriate information; specifically in relation to:
  - The counselling of patients and relatives / carers regarding the risks and benefits of transplantation
  - Explanation of tests, procedures and results
  - Outcome of assessment and review to be documented in a letter to the patient detailing discussions and agreed shared decision reached, including those patients who are not suitable
  - Information and education about immunosuppressive therapy

Safe, effective, evidence-based care, delivered through effective pathways of care, in particular through the provision of:

- detailed recipient assessment (including cardiac assessment) and annual transplant focused review whilst on the transplant list
- a surgical assessment of each patient prior to being placed on the national transplant list
- H&I assessment pre- and post-transplant
- timely operating theatre and relevant staffing availability to ensure optimal cold ischaemia times
- effective immunosuppressive therapy
- effective preventive therapy to control infections
- prevention / management of long term conditions and co-morbidities particularly with respect to cardiovascular disease, infection and cancer
- post-transplantation follow up
- long term follow up.

Specialist transplant centres will have a process / system to ensure that;

- patients are added to the waiting list and that the list is regularly reviewed and updated
- small bowel offers from NHSBT are reviewed in a timely manner
- the requirements of the European Union (EU) Organ donation Directive are met.

NHS Outcomes Framework Domains

| Domain 1 | Preventing people from dying prematurely | √ |
| Domain 2 | Enhancing quality of life for people with long-term conditions | √ |
| Domain 3 | Helping people to recover from episodes of ill-health or following injury | √ |
| Domain 4 | Ensuring people have a positive experience of care | √ |
| Domain 5 | Treating and caring for people in safe environment and protecting them from avoidable harm | √ |
### 4.2 Indicators Include:

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<th>Number</th>
<th>Indicator</th>
<th>Data Source</th>
<th>Outcome Framework Domain</th>
<th>CQC Key question</th>
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<td>Number of adult intestinal transplants</td>
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<td>Median cold ischaemia times</td>
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<td>90-day patient survival (%) for adult elective first intestine transplants</td>
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<td>1 year patient survival (%) for adult elective first intestine transplants</td>
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<td>% graft survival at 90 days</td>
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<td>effective</td>
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<td>% graft survival at one year</td>
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<td>1,2,3</td>
<td>effective</td>
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<tr>
<td>112</td>
<td>% graft survival at 5 years</td>
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<td>Responsive, caring</td>
</tr>
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<td>202</td>
<td>Patients are provided with information</td>
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</tr>
<tr>
<td>203</td>
<td>Patient experience is reviewed</td>
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<td>There are patient pathways in place</td>
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<td>006</td>
<td>There are clinical guidelines for follow up in place</td>
<td>Self declaration</td>
<td>1,2,3,5</td>
<td>effective, Safe</td>
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When considering which patients should be offered intestinal transplantation the factors are complex, but can in the main be distilled down to survival advantage and quality of life. Both are influenced by the underlying disease, complications of parenteral nutrition and the aspirations and psychological attitude of the patient.

The results of bowel transplantation continue to improve but remain somewhat inferior to other common organ transplants such as liver or kidney transplantation. The recovery time is also significantly longer after intestine transplantation. Quality of life (QoL) outcomes are vital parameters and it is expected that all providers will continue to work together to agree and collect QoL data to enable analysis of QoL benefits and dis-benefits for transplant patients.

The levels of immunosuppression medicines required after intestinal transplantation may be greater than prescribed for other transplants. Acute rejection is commonly seen after transplantation and requires additional treatment with immunosuppression medication, usually with large doses of corticosteroids. A small proportion of patients develop late rejection several months or years after transplantation and sometimes the bowel transplant needs to be removed. The service includes those patients requiring repeat transplantations.

Intestine transplant patients are also more prone to develop some additional complications including opportunistic viral infections, graft versus host disease, post-transplant lymphoproliferative disease amongst other issues.

There has been improved survival following intestinal transplantation with advances in surgical techniques and improved understanding of the monitoring and treatment of rejection and opportunistic infections. Approximately two thirds of patients make a long term recovery and around 90% of these patients are off intravenous feeding.

The service will be expected to provide accurate timely data to NHSBT. This will enable NHS England to monitor outcomes. Adult outcomes in the service are monitored continuously by NHSBT and discussed at its Multivisceral and Composite Tissue Advisory Group (MCTAG), in order to make recommendations on future management. The provider is expected to action any such recommendations in a timely manner.

Before listing for intestinal transplantation, it is expected that cases will have been considered at the National Adult Small Intestinal Transplantation (NASIT) forum. If the urgency of the case precludes planned discussion in this way, then communication between relevant clinicians in the clinical units should take place to ensure that the clinical plan is approved. This ensures that each case receives the benefit of the experience of a large body of expertise in the field. The role of NASIT is advisory and clinical responsibility for patient management remains with the individual transplant unit / clinician. Provider units must contribute to NASIT.

The provider will ensure that practitioners are compliant with continuous professional development requirements. By exception providers should alert commissioners to difficulties in succession planning.

**Detailed definitions of indicators, setting out how they will be measured, is included in schedule 6.**
4.3 Commissioned providers are required to participate in annual quality assurance and collect and submit data to support the assessment of compliance with the service specification as set out in Schedule 4A-C

4.4 Applicable CQUIN goals are set out in Schedule 4D

5. **Applicable Service Standards**

5.1 **Applicable Obligatory National Standards**

NICE Quality Standards: Patient Experience in Adult NHS services (2012)
Human Tissue Authority (HTA) guidance for Transplant Teams and Independent assessors (2014)

- Providers will meet standard NHS governance requirements.
- Providers will comply with the agreed transplantation policies and guidance of NHS Blood and Transplant and the Multivisceral and Composite Tissue Advisory Group.
- There is a requirement to hold national audit meetings involving all designated centres on an annual basis.

Each centre must ensure that:

1. All practitioners participate in continuous professional development and networking.
2. Patient outcome data is recorded and audited across the service.
3. All centres must participate in the national audit commissioned by NHS England.

Audit meetings should address:

- Clinical performance and outcome
- Process-related indicators e.g. efficiency of the assessment process, prescribing policy, bed provision and occupancy, outpatient follow up etc
- Stakeholder satisfaction, including feedback from patients, their families, referring clinician and GPs
- Equity of access to services
- Learning from peer review.

5.2 **Other Applicable National Standards to be Met by Commissioned Providers**


5.3 **Other Applicable Local Standards**

Not applicable.

6. **Designated Providers (if applicable)**

Cambridge University Hospitals NHS Foundation Trust
Oxford University Hospitals NHS Foundation Trust
## 7. Abbreviation and Acronyms Explained

The following abbreviations and acronyms have been used in this document:

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
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<tbody>
<tr>
<td>AMR</td>
<td>Antibody mediated rejection</td>
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<tr>
<td>CCGs</td>
<td>Clinical Commissioning Groups</td>
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<tr>
<td>CPA</td>
<td>Clinical Pathology Accreditation</td>
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<tr>
<td>DSA</td>
<td>donor specific antibodies</td>
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<tr>
<td>H&amp;I</td>
<td>Histocompatibility and Immunogenetics</td>
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<td>HLA</td>
<td>Human leukocyte antigen</td>
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<td>HPN</td>
<td>Home parenteral nutrition</td>
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<tr>
<td>HTA</td>
<td>Human Tissue Authority</td>
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<tr>
<td>MDT</td>
<td>Multidisciplinary team</td>
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<td>MCTAG</td>
<td>Multivisceral and Composite Tissue Advisory Group</td>
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<td>NASIT</td>
<td>National Adult Small Intestinal Transplantation forum</td>
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<td>QoL</td>
<td>Quality of Life</td>
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<td>TPN</td>
<td>Total parenteral nutrition</td>
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<tr>
<td>UKAS</td>
<td>United Kingdom Accreditation Service</td>
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