Professor Peter Johnson
National Clinical Director for Cancer
NHS England and NHS Improvement
Wellington House
135-155 Waterloo Road
London
SE1 8UG

02.06.2025

Dear Professor Johnson,

We are writing to NHS England, on behalf of the UK SACT Board and the Immuno-Oncology Clinic Network (IOCN), to raise a concern about access to funding of immunosuppressant medicines used to manage the adverse effects of immune-checkpoint inhibitors (ICIs).

Importantly it is acknowledged that this issue affects all four UK Nations, however, given there is not a singular over-arching governing body covering the four Nations, initial engagement with NHS England was considered to be the most appropriate approach.

ICIs have revolutionised the management of a wide range of cancers and are now in routine use across multiple disease sites. They have transformed outcomes for patients, in many cases leading to durable responses. Ten-year overall survival data are now available for cancers that were rapidly fatal prior to the use of ICIs[1].

Currently, one third of all Cancer Drugs Fund requests include treatment with an ICI, either alone or in combination with other systemic anti-cancer therapies (SACT).[2] These are represented by 9 different ICI therapeutics across 16 different tumour sites, with use in the neoadjuvant, adjuvant, peri-operative, maintenance and metastatic settings. Usage is increasing at around 25% each year and with it the incidence of toxicity. In addition to this there is a mortality risk associated with irAEs in patients being treated across settings who may either curative or long-term control from a malignant perspective, in whom access to potentially life saving treatment is variable and not secure.

The mechanism of action of ICIs puts patients at risk of immune-related adverse effects (irAEs). In patients treated with combination treatments 59% experience grade 3-4, severe toxicity whilst this is the case for 10-25% of patients on a single agent ICI treatment. The management of irAEs is described in international guidelines [3] ,

including the use of second- and third-line agents for patients with steroid refractory disease, with many Trusts developing local guidelines[4] in line with these, reflecting best practice principles.

The initial treatment of the majority of irAEs is with corticosteroids. A small proportion of patients have a steroid refractory irAE and require addition of a second/third line immunosuppressants, which increasingly includes biologic agents. Use of these subsequent agents is urgent and may be necessary to reduce the risk of irreversible organ damage and toxicity associated mortality.

Data are evolving with regard to the choice and efficacy of second and subsequent line immunosuppressants. It is recognised that currently there is a paucity of evidence from randomised clinical trials and most data are available from real-world experience and expert consensus opinion. However, in a number of cases, there is evidence and approval for these agents for the autoimmune/autoinflammatory condition that irAEs are mimicking, with proven efficacy and reimbursement. To reduce the risk of a fatal outcome from treatment-related toxicity, it has become necessary for oncologists to utilise this available expertise and experience when choosing which drugs to use with benefit demonstrated consistently in patient cases and case series.

Many of these immunosuppressive agents are “high-cost” but, unlike SACT, they are locally commissioned. This has led to an uncomfortable and unacceptable geographical disparity in terms of access. For example, in IR-colitis patients in Wales and Scotland are eligible to be treated with both infliximab and vedolizumab,[5] whereas access to infliximab is variable between regions and work recently carried out by BOPA illustrates difficulty in accessing vedolizumab across England.[6] In addition, tocilizumab for management of CRS (cytokine release syndrome) is commissioned alongside CAR-T and other bispecific drugs, but not for CRS that results from ICIs. International guidelines and cases of use suggest both infliximab and tocilizumab, alongside others, have a potential life-preserving role across multiple additional irAEs. However, gaining access and approval to use them in these broader indications is challenging at best.

In many cases, local applications must be made to Drugs and Therapeutics Committees (DTC) and/or Integrated Care Boards/Integrated Medicines Optimisation Committees (ICB/IMOC) to use these drugs on an individual basis. Given the time-critical nature of many of these scenarios, any delay in accessing these drugs risks a delay in treatment and deleterious impact on patient care. In addition, the approval of these therapeutics is increasingly challenging, and approval is by no means assured,

resulting in the potential for not only geographical variation but patient to patient variation within a region.

Individuals and providers have raised concerns with the IOCN and UK SACT Board regarding this difficult and inequitable situation. As stakeholder organisations, we entirely acknowledge that access to high-cost medicines for which there is limited evidence requires careful consideration and a governance process. In addition, it is worth considering that as more of these drugs become available as a generic/biosimilar, they may in fact be a more judicious use of NHS resource, than prolonged inpatient treatment, as well as increasing recognition of the associated complications from use of high dose corticosteroids in this patient population.

Collectively we would propose working collaboratively with NHS England to create an appropriate standardised framework within which to manage access to second, and further line, immunosuppressive treatments to allow this inequity to be addressed and patient outcomes to be optimised. This would be of mutual benefit to commissioners, providers and most importantly patients. We would therefore like to request a meeting to discuss this proposal further and look forward to hearing from you.

Yours Sincerely

Dr Clare Barlow (IOCN SACT Board Representative and IOCN Trustee)

Dr Anna Olsson-Brown (CEO, IOCN)

Mrs Alice Tew (IOCN Trustee)

Dr Kate Young (IOCN Trustee and ACP UKAOS Representative)

On behalf of the Immuno-Oncology Clinical Network (IOCN) and the UK SACT Board

The UK SACT Board is a national committee with representation and support from multiple stakeholders in support of this letter. They include:

Association of Cancer Physicians (ACP)

Royal College of Radiologists (RCR)

UK Oncology Nursing Society (UKONS)

British Oncology Pharmacy Association (BOPA)

Royal College of Physicians (RCP)

Cc Dr Anne Rigg

(By email)

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[1]. Wolchok J, Chiarion-Sileni V, Rutowski P et al Final, 10-Year Outcomes with Nivolumab plus Ipilimumab in Advanced Melanoma *NEJM* 2025;392:11-22

[2]. National Cancer Drugs Fund List version 1.342 NHS England » Cancer Drugs Fund list Accessed 15/01/2025

[3]. Haanen J, Obeid M, Spain L et al Management of toxicities from immunotherapy: ESMO Clinical Practice Guideline for diagnosis, treatment and follow-up. Annals of Oncology, Volume 33, Issue 12, 1217 – 1238

[4]. The Clatterbridge Cancer Centre Immunotherapy guidance Access ed Immunotherapy guidance :: The Clatterbridge Cancer Centre on 15/01/2025

[5]. Vedolizumab for ICI-induced enterocolitis - All Wales Therapeutics and Toxicology Centre Accessed 15/01/2025

[6] Coe F, Desai M, Kantilal K, et al Access to Vedolizumab for the management of immune-related colitis (IRC) - A United Kingdom study. Abstract presented at ESMO-IO December 2024