NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

HealthTech Guidance

GID-MT605 Digitally enabled therapy for chronic tic disorders and Tourette Syndrome

Final scope – updated

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1 Technologies

1.1 Purpose of the technologies

NICE is evaluating the possible cost and clinical effectiveness of digitally enabled therapy as an intervention for people with chronic tic disorders and Tourette Syndrome. This is due to the potential benefit of digitally enabled therapy in addressing the significant unmet needs of the population. Current guidance recommends that children or young people with tic disorders, that significantly interfere with their ability to function in their daily lives, should be referred to specialist mental health services, neurodevelopmental teams or for neurological assessment (NICE Guideline 127, 2023). Adults with a tic disorder should be referred for psychological therapy if the disorder is troublesome, or accompanied by additional progressive neurological symptoms (NICE Guideline 127, 2023)

Accepted evidence-based treatment options for diagnosed tic disorders are psychoeducation as a first line and behavioural therapies for those who continue to report difficulties with their tic disorder. For some people behavioural approaches may not be as effective, feasible or accessible and medications will be discussed as a possible treatment option with or without behavioural therapies.

Behavioural therapies for tic disorders include habit reversal therapy, comprehensive behavioural intervention for tics (CBIT) and exposure and response prevention therapy (ERP). However, due a shortage of trained therapists, behavioural therapy is only being offered at a small number of specialist treatment centres. As a result, experts estimate less than 20% of children and young people with tic disorders currently have access to behavioural therapies (Marino et al, 2023). Due to the varied expertise, access and availability of services across the UK, digitally enabled interventions may improve access as well as equity of access to treatment options for people with tic disorders.

1.2 Description of the technologies

The scope focuses on digitally enabled therapies intended for children and young people with tic disorders that:

- Have appropriate regulatory approval or are actively working towards regulatory approval, for example CE mark / UKCA mark and DTAC compliance
- Are available or working towards being available to the NHS
- Have online guided contact with a practitioner as part of the programme, or clinician oversight with the intervention for user safety.

In total 2 digitally enabled technologies for chronic tic disorders have currently been identified as in scope:

Online Remote Behavioural Treatment for Tics, **ORBIT (Mindtech)** is an online therapeutic intervention which aims to reduce tic severity in children and young people with tic disorders. The ORBIT treatment programme was developed from a previous platform (BIP TIC) in Sweden. ORBIT provides a form of behavioural therapy called exposure and response prevention (ERP), which is guided with an online therapist across a 10-week program. It is delivered on a secure internet platform and includes self-help guided chapters including chapters covering tic psychoeducation followed by exposure and response prevention behavioural therapy tasks. It also includes separate chapters for parents and care givers to further

support their role. The programme teaches users to suppress their tics while tolerating the urges to tic. The therapist has 10 to 20 minutes of contact time with the family each week and promotes engagement with the intervention as well as answering any questions. ORBIT has been studied as part of National Institute of Health and Care Research (NIHR) funded UK based trials, which have reported it to be a clinically and cost-effective intervention at up to 18 months (Hollis et al, 2021, Hollis et al, 2023). ORBIT does not require CE marking as it is not considered a software as a medical device. The company are working towards DTAC compliance currently as part of the NIHR Invention for Innovation Programme.

Neupulse (Neurotherapeutics) is a wearable digital wrist device which uses a novel approach utilising neuromodulation to produce median nerve stimulation (MNS). The device is reported to result in a reduction in tic frequency, tic severity and associated urges both whilst the device is active and in a follow up period without device activated (pre-publication available Morera et al, 2023).

The device requires no active effort by the user but worn when the user wants to feel more control of their symptoms. It is proposed for children and young adults aged 12 and over (due to the size of the wrist) as well as for adults with suspected or diagnosed Tourette Syndrome or a chronic (motor or vocal) tic disorder. Guidance alongside the device will include written and video-based material and a technical support helpline. The device has a corresponding phone app which can be used to generate a document of changes in symptoms for clinical oversight.

Neupulse is currently in further development and working towards CE and UKCA marking. It is estimated that the device will be available in 2026 (depending on regulatory approval). Evidence has been collected as part of a UK parallel double-blind sham-controlled trial for the reduction of tics in individuals with tic disorder (pre-publication available Morera et al, 2023).

2 Relevant conditions

These technologies are intended for people who have diagnosed chronic primary tic disorders. Tics are fast, repetitive muscle movements that result in difficult to control body movements or sounds. This can be described as an unpleasant sensation, commonly called an “urge” that only goes away when the tic is performed. Tics may involve body movements (motor) or sounds (phonic), or both. Examples of tics might include blinking, grimacing, head jerking, head banging, finger clicking, coughing, grunting, sneezing, repeating a sound or phrase (in approximately 10% of people this can be something offensive, such as swearing). The body movement or sound produced are the visible aspect of tics, but people describe many tics that are not visible to others. Tics are commonly associated with anxiety disorders. They can also lead to significant pain and discomfort which may worsen with tiredness or at times of high emotion such as stress.

Primary tics are more common in boys than girls (at a ratio of 4 to 1). Typically, primary tics begin between 4 and 6 years of age, can peak in early adolescence and decrease naturally into early adulthood. However, for a minority of adults their tic disorder does not reduce significantly, and some continue to experience a severe and debilitating form of tic disorder. It is common for people with Tourette syndrome to have comorbidities, with some studies reporting up to 90% of the population presenting with one or more co-occurring condition (Eapen at al, 2022). These may include neurodiverse conditions such as attention deficit / hyperactivity disorder (ADHD), obsessive compulsive disorder (OCD) and autism spectrum disorder (ASD) as well as anxiety disorders and feelings of low mood and depression. The impact of tics can be variable, affecting academic, social, occupational, and physical functioning. Young people with tic disorders commonly report extensive stigma, feelings of isolation and bullying. Without adequate support tic disorders can significantly affect various aspects of the person’s life, contributing to a reduced quality of life. Having long-standing tics is also associated with a reduction in life expectancy and a fourfold increased risk of death by suicide (Marino et al, 2023).

3 Current management and care pathway

Currently there is no clinical guideline for the assessment and treatment of tic disorders in the UK. Guidelines have been published recently from the European Society for the study of Tourette syndrome (ESSTS) (Muller-Vahl et al, 2023) and BMJ best practice for tic disorders (Pringsheim, 2022) and Tourette's syndrome (Grados, 2023) see Appendix A.

Symptoms of tics may be identified by the person themselves, by parents, carers, peers or in school settings. For children and young people presenting in primary care a watch and wait approach is typically taken for those with simple tics without functional impairment (NG127).

For people who are having difficulties with a tic disorder a referral should be made to an appropriate secondary or tertiary service (depending on the presentation, comorbidities, and local specialist clinics). Referrals may be made to mental health services, neurodevelopmental teams, paediatric or neurology teams dependent on local services.

Diagnosis should be made by a comprehensive clinical history as well as a general medical and neurological examination. Tic disorders are classified according to the type of tic present and the duration of the tics. Tics can be categorised as functional tic-like behaviours or primary tics (also known as neurological tics). Functional tics can start suddenly with no apparent cause, it is common for them to present as complex tics initially and more often are associated with anxiety. Primary tics tend to present as simple tics initially and become more complex over time.

Tics can be transient, lasting less than 1 year, commonly known as provisional tics. Or they can persist over a year and be classified as a chronic tic disorder (when either motor or vocal tics are present). When both motor and vocal tics are present for more than 1 year, this is commonly known as Tourette syndrome. In the UK, Tourette Syndrome is identified in 1 per 100 school children (BMJ, 2023).

Initial intervention for all tic disorders is psychoeducation. This should be extended to family, teachers, and peers in order to reduce any associated stigma and distress. For some people no further treatment will be needed.

Assessment of possible comorbid disorders should also take place with consideration of their possible contribution in impacting functional capacity at home, school, in the workplace and with peers (BMJ, 2023). If other conditions are present referral to a psychiatrist may be appropriate for further evaluation and treatment.

For those who continue to have bothersome tics despite psychoeducation, further treatment is indicated. Current evidence-based options include behavioural therapies with or without medication. Evidence based cognitive behavioural approaches should be the first line for children and young people, these include: comprehensive behavioural intervention for tics, habit reversal therapy, and exposure and response prevention therapy. Experts advised that children aged 8 and under typically are unlikely to be able to reliably identify urges, which is required to have positive outcomes with behavioural therapy.

Medication should be considered if behavioural interventions have not been effective or have been deemed inappropriate. There are a number of pharmacological options which may be prescribed with or without continued therapeutic intervention. Treatment must be tailored to each individual's needs (BMJ, 2023).

More novel treatment options are being studied for tic disorders, including Median Nerve stimulation and deep brain stimulation. However an NHS England review of the evidence base for deep brain stimulation as a treatment option for adults with refractory Tourette Syndrome concluded that there is not sufficient evidence to support its routine commissioning (NHS England, 2018).

4 Scope of the assessment

This evaluation is for people with chronic tic disorders and Tourette Syndrome who continue to report bothersome tics after initial psychoeducation. This evaluation does not consider provisional tics or functional tics, except for those that occur alongside primary tics.

Table 1 Decision problem

Decision question	Does digitally enabled therapy for people with chronic tic disorders and Tourette Syndrome represent a clinically and cost-effective use of NHS resources?
Population	People with a diagnosed primary tic disorder that have had access to psychoeducation, however their tics continue to be bothersome to them. Children and young people aged 12 and over are indicated for Neupulse.
Subgroups	If the evidence allows, the following subgroups may be considered: • Children and young people • Adults • People with diagnosed comorbidities including: Attention deficit / hyperactivity disorder (ADHD), autism spectrum disorders (ASD)and obsessive compulsive disorder (OCD), anxiety disorders and depression.
Interventions (proposed technologies)	• ORBIT (MindTech) • Neupulse (Neurotherapeutics) These interventions should only be considered provided the person (and parent or carer where appropriate) have had access to a form of psychoeducation. If the tic disorder continues to cause difficulties for the person, a clinician may consider referring for these proposed interventions. The Neupulse device is currently intended for use in adults and children aged 12 or over.
Comparator(s)	Standard care should include psychoeducation and face to face behavioural therapy. However, there may be a considerable waiting time, distance to travel or lack of access to specialist behavioural therapy.
Healthcare setting	Secondary or tertiary care settings, which may include children and young people's mental health services (CYPMHS), community mental health teams (CMHTs), community paediatrics, secondary care paediatrics, neurology or neurodevelopmental teams including neurologists, neuropsychologists, psychiatrists and psychologists.
Outcomes	Outcome measures to consider include: **Intermediate measures** • Intervention related adverse events

	• Treatment satisfaction and engagement • Intervention adherence, rates of attrition and completion **Clinical outcomes** • Measures of symptom severity (self, parental or practitioner reported) such as YGTSS, TTSS, CGI-I, CGAS, PUTS-9, Parent tic scale • Tools for depression and anxiety such as Patient Health Questionnaire for adolescents, Childrens depression inventory and the Beck depression inventory • Social, behavioural, and functional outcomes including measures such as educational attendance and attainment and work engagement • Suicidal thoughts and behaviour, adverse events. **Patient reported outcomes** • Health related quality of life such as GTS-QOL, pain and sleep measures • Patient experience and satisfaction • Rates and reasons for adherence / attrition. **Costs** will be considered from an NHS and Personal Social Services perspective. Costs for consideration may include: • Cost of technologies, including licensing fees • Cost of other resource use (associated with managing tics, adverse events or complications) including: – GP appointment, mental health support team / CYMHS appointments – Health care professional training, grade, and time for providing regular support and guidance for the users of the digitally enabled technologies. Any economic data on technologies cost effectiveness, ICER statistics will be considered if reported.
Economic analysis	A health economic decision model will be developed comprising a cost effectiveness analysis. Costs will be considered from an NHS and Personal Social Services perspective. Sensitivity and scenario analysis should be undertaken to address the relative effect of parameter or structural uncertainty on cost-comparison estimates. The time horizon should be long enough to reflect all important differences in costs or outcomes between the technologies being compared.

4.1 Other issues for consideration

- Technologies are heterogenous in various ways including:
  - Type of intervention: Behavioural therapy (ERP in ORBIT). Behavioural therapy is an evidence-based treatment option for tic disorders. Median nerve stimulation (used in Neupulse) remains a novel approach.
  - Technologies are at different stages in development (Neupulse is still in development), which will impact on the levels of evidence currently available and vary the evidence of use in the NHS. This assessment will look across a range of evidence types including evidence of clinical effectiveness.
  - Delivery mode (computer, app, wearable devices), access (referred or self-referrals), intended population (varies in age groups and exclusion criteria), practitioner or parental supported, having therapist guidance, data that has been collected and current regulatory status all vary across the technologies.

- Given the large differences in interventions and approaches consideration must be given to the service costs, workforce burden, set up and maintenance costs as well as software update requirements for each individual intervention.

- A large proportion of this population are likely to have additional diagnosed or undiagnosed neurodevelopmental conditions including OCD, ADHD and autism spectrum disorders (ASD).

- People with chronic tics are at higher risk of death by suicide.

4.2 Equality considerations

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others.

- Tic disorders is more common in boys than girls at a ratio of 4:1

- Patient-facing digital health technologies may be unsuitable for people with cognitive impairment, problems with manual dexterity or learning disabilities. Carer or advocate assistance may be required to navigate the program and consideration of this should be made by the company as well as the referring practitioner when considering appropriate intervention for the child or young person. Further considerations can be found in NICE Guidance on mental health problems in people with learning disabilities (NG54, 2016).

- People, or their families / carers, with English as a second language may have difficulties navigating digital technologies provided in English.

- Peoples ethnic, religious and cultural background may affect their views of digital health interventions. Healthcare professionals should discuss the language and cultural content of digital health interventions with users before provision.

- People from lower socioeconomic backgrounds may find it difficult to engage in therapeutic material given the time demands of the programs.

- Patient facing digital health technologies should ensure their program is accessible for screen readers (people with visual impairments) and those with hearing impairments.

- Specific groups may particularly benefit from improved access to online behavioural therapy, for example:
  - Those living in areas not currently served by specialist clinical centres might have difficulty travelling to face-to-face appointments if public transport is unreliable, costly and if parents are unable to drive them.
  - Adolescents may have an increased engagement with this format of intervention.

  - People from lower socioeconomic groups may lack the financial support required to ensure that they attend face to face sessions.

  - Some children and young people may not have the family support needed to ensure that they attend face to face sessions. These children and young people may also have less support to seek help in the first place or to navigate the healthcare system.

- However, accessibility would not be improved for those who are unable to engage with a digital service due to a lack of equipment, unavailability of internet connection or lack of experience with computers or lack the privacy needed to complete this intervention. Additional support and resources may be needed for these individuals.

Chronic tic disorders and Tourette Syndrome can significantly affect people's daily living. Under the Equality Act 2010, a person has a disability if they have a physical or mental impairment that has a substantial and long-term effect on their ability to do typical day-to-day activities. Age, sex, disability, race and religion are protected characteristics under the Equality Act (2010).

4.3 Potential implementation issues

- The appropriateness of behavioural therapies or median nerve stimulation should be assessed on an individual basis.
- There is no national guideline in place for the treatment of tic disorders.
- There is high variation in services available to the population.

  Experts highlighted the importance that technologies have an online guided practitioner or clinical oversight, to ensure users had contact with a trained practitioner to promote engagement, motivation and accountability for improved outcomes. As well as being key for safety, in

order to ensure users who are not receiving benefit can be identified and supported as required.

5 Stakeholders

5.1 Healthcare professional organisations

The following healthcare professional organisations have been identified as stakeholders for this evaluation:

- Academy of British Neurologists
- Association of Child Psychotherapists
- Association of Educational Psychologists
- British Academy of Childhood disability
- British Association for Counselling and Psychotherapy
- British Association of Occupational Therapists and College of Occupational Therapists
- British Psychological Society
- British Paediatric mental health group
- British Paediatric Neurology Association
- British Psychotherapy Foundation
- Primary Care Neurology Society
- Royal College of Paediatrics and Child Health
- Royal College of Psychiatrists
- Royal College of Speech and Language Therapists
- UK Council for Psychotherapy
- Society for coaching psychology
- National CAMHS Support service / Children and Young peoples mental health service (CYPMHS)
- British Psychoanalytic Council
- British Association for Behavioural and Cognitive Psychotherapies (BABCP)
- Association of Psychoanalytic Psychotherapy in the NHS
- Association for Child and Adolescent Mental Health

- Counsellors and Psychotherapists in Primary care
- Mental Health nurses association
- Mental Health forum committee

5.2 Patient and carer organisations

NICE's Public Involvement Programme have identified the following patient and carer organisations for advice:

- Ambitious about autism
- Asperger foundation
- Autism East Midlands
- Autism Northern Ireland
- Challenging Behaviour Foundation
- Child autism UK (formerly known as Peach)
- National Autistic Society
- Mind
- Tourettes Action
- The Neurological Alliance
- The Brain charity

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Appendix A Related Guidance

- Suspected neurological conditions: recognition and referral (NG127), NICE Guideline, October 2023.
- BMJ Best Practice, Tic disorders 2022 Pringsheim, T
- BMJ, Best Practice Tourette Syndrome, 2023 Grados, M.
- European Clinical guidelines for Tourette syndrome and other tic disorders version 2.0. Part I assessment. 2022. Szelko, N., Robinson, S., Hartmann, A., Ganos, C., Debes, N., Skov, L., Haas, M., Rizoo, R., Stern, J., Munchai, A. Czernecki, V., Dietrich, A., Murphy, T., Martino, D., Tarnok, Z., Hedderly, T., Muller-Vahl, K., Cath, D.
- European Clinical guidelines for Tourette syndrome and other tic disorders Part II, interventions. 2022 Andren, P., Jakubovski, E., Murphy, T., Woitecki, K., Tarnok, Z., Zimmerman-Brenner, S., van-de-Griendt, J., Mol Debes, N., Viefhaus, P., Robinson, S., Roessner, V., Ganos, C., Szejko, N., Muller-Vahl, K., Cath, D., Hartmann, A., Verdellen, C.
- European clinical guidelines for Tourette syndrome and other tic disorders- version 2.0. Part IV: deep brain stimulation 2022 Szejko, N., Worbe, Y., Hartmann, A., Visser-Vandewalle, V., Ackermans, L., Ganos, C., Porta, M., Leentjens, A., Mehkrens, J., Huys, D., Baldermann, J., Kuhn, J., Karachi, C., Delorme, C., Foltynie, T., Cvanna, A., Cath, D., Muller-Vahl, K
- Practice guideline recommendations summary: Treatment of tics in people with Tourette syndrome and chronic tic disorders, 2019. Pringsheim, T., Okun, M., Muller-Vahl, K, Martino, D., Jankovic, J., Cavanna, A., Woods, D., Robinson, M, Jarvie, E., Roessner, V., Oskoui, M., Holler-Managan, Y., Piacentini, J.
- Canadian Guidelines for the Evidence-Based Treatment for Tourette Syndrome, 2012. Billinghurst, L., Carroll, A., Day, L., Dion, Y., Doja, A., Gorman, D., Luscombe, S., McKinlay, D., Pringsheim, R., Sandor, P., Steeves, T

Appendix B Abbreviations

ADHD	Attention deficit / hyperactivity disorder
ASD	Autism spectrum disorder
CBIT	Comprehensive Behavioural Intervention for tics
CYPMHS	Children and young people mental health services
DTAC	Digital Technology Assessment Criteria
ERP	Exposure and response prevention therapy
ESSTS	European Society for the study of Tourette syndrome
ICER	Incremental Cost-Effectiveness Ratio
OCD	Obsessive compulsive disorder
PUTS	Premonitory urge of tics scale
TTSS	Total Tic Severity Score
YGTSS	Yale Global Tic Severity Scale