

CoverScan

Category:

Best Medical Technology

Company Name:

Perspectum

Product/Solution Name:

CoverScan

Compound/Tech Name:

CoverScan

Trade Name:

CoverScan

Corporate Name:

CoverScan

Date of Approval:

2022-05-19

Indications:

CoverScan is indicated for the comprehensive evaluation of patients with or at risk of multi-organ disease. By quantifying tissue characteristics, fat distribution, and potential inflammatory or fibrotic changes in a single MRI session, it addresses three principal needs:

- **Diagnosis**
 - Identifies subclinical organ dysfunction in metabolic diseases (e.g., type 2 diabetes, nonalcoholic fatty liver disease), post-viral syndromes (e.g., long COVID), or systemic autoimmune conditions such as lupus, and infiltrative disorders like amyloidosis.
 - Uncovers silent disease manifestations frequently missed by traditional, organ-specific modalities, allowing for earlier, more accurate detection before irreversible damage occurs.

- Risk Stratification of Disease Severity

- Enables clinicians to categorize patients based on organ involvement and severity of tissue changes, including steatosis, fibroinflammation, or other pathological alterations indicative of disease progression.

- Assists in determining the urgency and intensity of therapeutic interventions-whether lifestyle modifications, pharmacotherapy, or specialist referral-based on individual risk profiles.

- Clinical Decision Support

- Provides quantitative biomarkers spanning the heart, liver, kidneys, pancreas, spleen, and body composition, facilitating ongoing assessment of disease progression or regression.

- Supports the evaluation of new and existing treatments, including advanced metabolic drugs (e.g., GLP-1 receptor agonists) and immunomodulatory therapies used in conditions such as lupus, amyloidosis, or chronic inflammatory syndromes.

- Delivers structured, cloud-based reports seamlessly integrated into care pathways, enabling multidisciplinary collaboration and data-driven treatment planning.

By offering a multi-organ perspective in a single imaging session, CoverScan fulfils a critical need for diagnosing, stratifying, and guiding the management of complex metabolic, inflammatory, and infiltrative conditions-ultimately helping to optimize patient outcomes and resource utilization.

Therapeutic Areas:

Metabolic disorders - obesity, type 2 diabetes, metabolic syndrome

Post-viral sequelae - Long COVID

Autoimmune disease - systemic lupus erythematosus

Haematologic malignancies - leukaemias, lymphomas

General Information File Document upload:

N/A

Background information and need for drug / device:

Obesity affects over 40% of American adults and is now recognized as a complex, multi-organ disease. Oncology indications are similarly prevalent but have been transformed by precision health approaches tailoring treatments to individual risk profiles, dramatically improving outcomes. Yet, this personalized approach remains

underutilized in managing obesity, despite mounting evidence that comorbidities, critically shape treatment response and prognosis.

In a landmark development earlier this year, the Lancet Commission redefined clinical obesity as a chronic disease characterized by excess adiposity that causes abnormalities in organ function and structure. This marks a pivotal shift away from viewing obesity as a lifestyle issue, reframing it as a systemic condition which requires integrated, personalized management. To deliver on this new paradigm, clinicians and pharmaceutical companies need scalable tools that evaluate multiple organs, metabolic indicators, and inflammatory markers in a single, accessible workflow. CoverScan, a multi-parametric MRI solution, fulfills this need by providing a comprehensive view of inflammation, fibrosis, fat and function across multiple organs - including the liver, heart, pancreas, and kidneys - alongside insights into body composition. Designed for efficiency and precision, CoverScan streamlines diagnosis, supports targeted therapy selection, and enables longitudinal monitoring of treatment response, all via Perspectum's SaaS platform.

Emerging evidence reveals that patients with obesity respond differently to therapies based on their comorbid profiles. Pharmaceutical companies increasingly recognize obesity as a complex, multiorgan condition and not simply one of weight. As a result, they are developing targeted treatments not just for obesity alone, but for specific comorbidities such as heart failure, chronic kidney disease, and sleep apnea. Examples of this are Novo Nordisk's semaglutide (Ozempic/Wegovy) with FDA approvals for type 2 diabetes, obesity and overweight, and cardiovascular disease and chronic kidney disease in patients with type 2 diabetes and is currently under review for approval in metabolic associated steatohepatitis; and Eli Lilly's tirzepatide with approvals for type 2 diabetes, obesity and overweight, and obstructive sleep apnea. As treatment options become more tailored and sophisticated, precision health is no longer optional; it is central to addressing the growing global burden of metabolic disease and ensuring every patient receives the optimal treatment.

The use of CoverScan in pharmaceutical trials allows pharmaceutical companies to gain insights into the multi-organ benefits of their candidate drug within a single trial and for enhanced evaluation of potential drug-related adverse events, such as muscle wastage and pancreatitis. This supports in early planning of expanded label claims, IP portfolios, and supports accelerated approvals by capturing multi-organ efficacy data earlier. Additionally, the enhanced safety monitoring CoverScan enables facilitates early termination of development programs if serious safety signals occur.

In the clinical setting, CoverScan helps shift chronic disease care from reactive to proactive, which allows for earlier treatment and better patient outcomes. CoverScan can detect mild organ abnormalities in patients with early disease, such as metabolic syndrome, pre-diabetes or pre-clinical obesity. This enables timely intervention before these abnormalities progress to chronic disease, which imposes a significantly larger burden on healthcare resources, the economy and society as a whole.

Background File Document upload:

N/A

History of the development of the solution/product:

When the World Health Organization declared COVID-19 a pandemic in March 2020, Perspectum rapidly mobilized its imaging expertise to meet the urgent need for a scalable, non-invasive tools that could assess systemic effects of the virus. Drawing on its Oxford-based R&D infrastructure, Perspectum developed CoverScan-a rapid, whole-body MRI protocol capable of assessing the heart, lungs, liver, pancreas, kidneys, and spleen within a single, 30-minute scan. CoverScan received UK Exceptional Use Authorization in early 2021, later securing UKCA and FDA 510(k) clearance.

As long COVID emerged, CoverScan played a central role in community studies and clinical trials. A Perspectum-led study revealed nearly 70% of post-COVID individuals with persistent symptoms showed organ impairment, and over a quarter had multiorgan involvement. Follow-up work (Dennis et al., 2023) confirmed that damage may persist even after symptoms fade. In the STIMULATE-ICP trial - one of the world's largest randomized long COVID studies - CoverScan's rapid, multiorgan reports supported timely care decisions.

CoverScan's utility has since expanded to metabolic disease, where similar patterns of low-grade inflammation and multiorgan dysfunction exist. Perspectum added a body composition module to the technology to enhance phenotyping of these patients. Body composition analysis with CoverScan includes visceral and ectopic fat assessment alongside measurements of muscle volume and quality, which are crucial for understanding metabolic risk and treatment response.

This broader diagnostic capability is exemplified by the UK Imaging in Diabetes Study (UKIDS), which uses CoverScan alongside traditional biomarkers to capture the complex, multiorgan burden in type 2 diabetes. It enables the identification of subclinical dysfunction which is often missed using traditional biomarkers, supporting a precision medicine approach.

Further reinforcing CoverScan's relevance and utility in treatment monitoring is the Perspectum-funded MODIFY study, which evaluated individuals with metabolic disease using multiorgan MRI assessments. Published outcomes showed that even in patients with stable or well-managed type 2 diabetes, a significant proportion had early signs of organ dysfunction, particularly in the liver and cardiovascular system. The MODIFY study also followed the patients longitudinally as they received standard of care treatment for their type 2 diabetes, revealing that those receiving newer therapies, such as SGLT2is and GLP-1s, had greater improvements in visceral adiposity and liver inflammation than those on traditional glycemic lowering therapies, such as metformin.

These results underscore CoverScan's unique value in capturing both the full extent of disease burden and treatment-related improvements that standard glycemic control markers miss. This enables a more nuanced evaluation of cardiometabolic therapies and supports data-driven decisions in both clinical practice and trial design.

For clinicians and patients, this means earlier, more accurate diagnoses and better-tailored interventions. For pharmaceutical companies, CoverScan offers a scalable tool for evaluating efficacy and safety across organ systems, critical for accelerated approvals, expanding label indications and identifying early signs of adverse effects.

Development File Document upload:

N/A

Why this drug or device is innovative, the broad implications for future research, and/or how it will improve the human condition:

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Innovation File Document upload:

N/A

Please provide appropriate references (PubMed, Abstract, Website):

References attached

References File Document upload:

CoverScan Publications LATEST 2024.pdf
7 CoverScan Long Covid value dossier26.pdf